

Methods Report

*The International Guideline for the
Definition, Classification, Diagnosis
and Management of Urticaria*

EuroGuiDerm

Centre for Guideline Development

Methods Report

***The International Guideline for the
Definition, Classification, Diagnosis and
Management of Urticaria***

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NOTES ON USE/DISCLAIMER

This is the Methods Report for the International Guideline for the Definition, Classification, Diagnosis and Management of Urticaria.¹ Because the 2024 guideline is an update and revision of the EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline on urticaria published in 2021,^{2,3} some parts of this Methods Report will be identical or similar in wording to the previous methods report published in 2021.² Some of the wording will also be identical or similar to that in the methods section of the main guideline document,¹ which itself is a summary of the present Methods Report. This work is licensed under the Creative Commons Attribution-NonCommercial 4.0.

FUNDING

The International Guideline for the Definition, Classification, Diagnosis and Management of Urticaria is a joint initiative of the Global Allergy and Asthma Excellence Network (GA²LEN) and its Urticaria and Angioedema Centers of Reference and Excellence (UCAREs and ACAREs), the European Dermatology Forum (EDF), the Asia Pacific Association of Allergy, Asthma and Clinical Immunology (APAAACI), the American Academy of Dermatology (AAD), the British Society for Allergy & Clinical Immunology (BSACI), and the Gulf Academy of Allergy and Clinical Immunology (GA2CI). All of these organisations provided funding for the development of the guideline. There was no funding from other sources. The funders were not involved in the analysis of data or the writing of the Methods Report and the Evidence Report.

INTRODUCTION

This report presents the methods and processes used to develop the guideline. It also presents the evidence identified and generated through the systematic literature review and meta-analysis that underpin the recommendations of the expert panel. The guideline should be referenced as:

Zuberbier T, Abdul Latiff AH, Abuzakouk M, et al. The International Guideline for the Definition, Classification, Diagnosis and Management of Urticaria. Allergy. 2026 Feb 6. doi:10.1111/all.70210.

The EuroGuiDerm staff at the Division of Evidence-Based Medicine, Department of Dermatology, Venereology and Allergy, Charité – Universitätsmedizin Berlin conducted the evidence assessment, prepared the evidence-to-decision frameworks, facilitated the online voting, and co-prepared and co-facilitated the consensus conference.

Along with the Division of Evidence-Based Medicine, Katrin Ciupka¹, Mareike Stephan¹, and Katarina Stevanovic¹ supported the clinical coordination and carried out editorial work on the guideline documents.

INVOLVING STAKEHOLDERS AND FORMING THE GUIDELINE SUBCOMMITTEE

An email invitation to nominate experts to participate in the development of the guideline was sent to EAACI, GA²LEN, EDF, APAAACI, AAAAI, BSACI, ACAAI, AAD, GA2CI by guideline coordinator Marcus Maurer. Three societies, AAAAI, ACAAI, and EAACI either declined the invitation or did not reply. In parallel, an open call for registration for the expert panel and author group was published on the UCARE website (<https://ucare-network.com/guidelines>). The societies For the list of interdisciplinary experts

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and their countries, nominating societies, affiliation/specialties, see Table 1; for the members of the EuroGuiDerm methodologist group, see Table 2.

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Title	First name	Last name	Country	Nominating society	Affiliations	Role
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Title	First name	Last name	Country	Nominating society	Affiliations	Role
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Title	First name	Last name	Country	Nominating society	Affiliations	Role
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Title	First name	Last name	Country	Nominating society	Affiliations	Role
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Title	First name	Last name	Country	Nominating society	Affiliations	Role
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TABLE 2: MEMBERS OF THE EUROGUIDERM GUIDELINE METHODOLOGY GROUP

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Prof Dr.	Alexander	Nast	Germany	Division of Evidence-Based Medicine (dEBM), Charité – Universitätsmedizin Berlin	Senior methodologist

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DECLARATION AND MANAGEMENT OF CONFLICTS OF INTEREST

All nominated experts received an invitation to submit a declaration of their conflicts of interest (COIs) online and to self-declare their personal financial interests (PF), non-personal financial interests (N-PF), and personal non-financial interests (PN-F). Experts were asked to self-declare their interests via an online survey in the context of registering for the consensus conference. An overview of the declarations of personal-financial conflicts of interests is given in Table 3. In total, 124 declared that they had no PF COI (59.05%).

TABLE 3: DECLARATIONS OF PERSONAL-FINANCIAL CONFLICTS OF INTERESTS AS PROVIDED BY THE EXPERTS

Title	First name	Last name	Personal financial conflict of interest	COI for area
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Prof.	Mohamed	Abuzakouk	None	None
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Prof.	Mona	Al-Ahmad	None	None
Prof.	Abdullah	Alangari	None	None
Dr.	Hamad	Alhameli	None	None
Dr.	Ramzy	Mohammed Ali	None	None
Dr.	Cesar Daniel	Alonso Bello	None	None
Dr.	Saad	Alshareef	None	None
Dr.	Salem	Al-Tamemi	None	None
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Dr.	Susan	Aquilina	None	None
Dr.	Miriam	Araújo	None	None
Dr.	Rand	Arnaout	None	None
Dr.	Riccardo	Asero	Jasper therapeutics, Novartis, Sanofi	Therapy
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Prof.	Barbara	Ballmer-Weber	Novartis, Sanofi, Takeda	Therapy
Dr.	Christine	Bangert	Unspecified personal financial interests	Therapy, diagnostics
Prof.	Andrea	Bauer	Abbvie, Almirall, Amgen, AstraZeneca, Biofrontera, Blueberry Therapeutics, Celldex, Centogene, Escient, Galderma, Genentec, Incyte, Jasper, L'Oreal, Leo, Lilly, Novartis, Phavaris, Regeneron, Sanofi, Shire, Takeda	Therapy
Dr.	Moshe	Ben-Shoshan	Novartis, Sanofi	Therapy
Dr.	Jonathan	Bernstein	Allakos, Allergy Therapeutics, Amgen, Aretreia, Astria, AZ, Biocryst, Biomarin, Blueprint Medicine, Celldex, Cogent, CSL Behring, Eli Lilly, Escient, Evoimmune, Genentech, GLG guidepoint, GSK, Intellia, Ionis,	Therapy

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Prof.	Laurence	Bouillet	Unspecified personal financial interests	Therapy, diagnostics
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The following participants reported differential COI in the context of the guideline publication:

¹ CSL Behring, Grifols, Takeda

² Abbvie, Celltrion, Novartis, Sanofi

³ ALK, AstraZeneca, Bayer, Chiesi, Grunenthal, Grin, GSK, Karger, Viatris, Menarini, MSD, Novartis, Pfizer, Sanofi, Siegfried, Carnot, Syneos Health

⁴ Abbvie, Novartis, Sanofi, Janssen, UCB, Eli Lilly, Pfizer

⁵ AbbVie, Advanz, ALK-Abello, Allegría, Almirall, Amgen, Argencx, AstraZeneca, Astria, Attovia, Berlin-Chemie, Blueprint, Celldex, Celltrion, DeepApple, Escient, Ga2len, Galderma, GSK, Incyte, Jasper, Lilly, Novartis, Pfizer, Pharvaris, Regeneron, Sanofi, Santa Ana Bio, Septerna, Teva, ThirdHarmonicBio, Vifor

⁶ Sanofi, Abbvie, Leo Pharma, Gsk, Astra-Zeneca, Almirall, Stallergenes, Incyte, Celltrion, Pfizer

⁷ Abvie, Aimmune, ALK, Amgen, Astra-Zeneca, Celtrion, CSL Behring, DBV technologies, Eli Lilly, Genentech, Incyte, Leo Pharma, Novartis, Nuvo Pharmaceuticals, Pfizer, Sanofi, Regeneron

Active participation in the consensus conference required a declaration of interests. In accordance with the EuroGuiDerm Manual, members with personal-financial interests related to products being evaluated were excluded from voting on recommendations during the consensus conference for topics where their declarations indicated a conflict of interest.⁴ The following topics were distinguished to define relevance of COIs and manage participation in voting on recommendations: 1. diagnostic recommendations (recommendations Diag. 1-9), 2. treatment recommendations (recommendations Mgmt. 1-13 and Spec. 1-3). Employees working at companies with a commercial interest in products being discussed were generally excluded from voting on recommendations.

METHODS

DEFINING THE PURPOSE OF THE GUIDELINE

The aim of the guideline is to provide a definition and classification of urticaria, thereby facilitating the interpretation of divergent data from different centres and areas of the world regarding underlying causes, eliciting factors, burden to patients and society, and therapeutic responsiveness of subtypes of urticaria. Furthermore, the guideline provides recommendations for diagnostic and therapeutic approaches in common subtypes of urticaria.

SELECTING AND SPECIFYING GUIDELINE QUESTIONS

See the Methods Report² of the previous guideline updates for details on the processes used in 2016 and 2021 to (a) suggest an initial list of key questions for that update of the guideline, as well as to (b) have the expert panel vote on whether to include or exclude key questions from this initial list and (c) choose relevant outcomes a priori and have the expert panel rate these in terms of their importance.

At the initial stages of guideline development, the guideline coordinators used search trends analysis and artificial intelligence-assisted inquiries (Google Trends and ChatGPT) to identify previously unaddressed topics and key questions. The prompts for these inquiries were provided by the content experts Rafael José Vieira^{2,3} and Bernardo Sousa Pinto^{2,3}. For the 2024 update of the guideline, the guideline coordinators decided that the same key questions should be used as those developed for the version of the guideline published in 2021. Additionally, an online survey was conducted among the committee members, in which suggestions to revise or add new questions were collected. An updated list was prepared by the clinical and methodological guideline coordinators. Five new questions pertaining to novel treatments were introduced along with a question regarding biomarkers to predict the disease course. A previously included question on the use of higher than fourfold doses of second-generation antihistamines was removed due to robustly established evidence against their use. The list of key questions can be found in the guideline itself.

SEARCH METHODS, SEARCH RESULTS AND EVIDENCE SELECTION

SEARCH

The key questions were translated in the PICO format, which specifies the intervention, comparison and outcome used to assess efficacy and safety (see box 1). New and revised guideline questions were adopted accordingly. PICO is specified in the header of each evidence-to-decision framework.

- Systematic searches for randomized controlled trials and clinical, controlled trials were undertaken using the following databases on February 9, 2024 limiting the time to 2021 – February 9, 2024: Ovid MEDLINE(R) ALL
- Embase Classic + Embase
- Cochrane Central Register of Controlled Trials (CENTRAL)

All search strategies can be found in Appendix 1: Search Strategies. We did not search trial registries, grey literature sources, or contact authors due to resource limitations. EndNote 21™ was used to manage references.

Because the update of the International Guideline for Urticaria is an update of an existing guideline, we did not search for other guidelines or systematic reviews.

² MEDCIDS - Department of Community Medicine, Information and Health Decision Sciences; Faculty of Medicine, University of Porto, Porto, Portugal

³ CINTESIS@RISE - Health Research Network, MEDCIDS, Faculty of Medicine, University of Porto, Porto, Portugal

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ELIGIBILITY CRITERIA

The pre-selected inclusion criteria for the title/abstract and full-text screening are given in Box 1. The exclusion criteria for the title/abstract and full-text screening are given in Box 2.

BOX 1: PICO / INCLUSION CRITERIA

Population

- chronic spontaneous urticaria (CSU), chronic idiopathic/chronic urticaria
- chronic inducible urticaria (CIndU) [cold urticaria, pressure urticaria, heat urticaria, solar urticaria, symptomatic dermatographism (=urticaria factitia), vibratory angioedema, aquagenic urticaria, cholinergic urticaria, contact urticaria]
- angioedema without wheal

Interventions (stated with minimum standard dosage for adults where applicable):

- H1-antihistamines (H1-AH) 1st generation:
 - clemastine fumarate 1mg BID ($\pm$ 1,34mg clemastine fumarate), 20ml sirup BID ($\pm$ 1,34mg clemastinehydrogen fumarate = 1mg clemastine)
 - dimetindene maleate 0.05-0.1mg/kg BW QD ($\pm$ 1-2 dragees á 1mg dimetindene maleate), 1ml TID ($\pm$ 20 drops)
 - diphenhydramine
 - hydroxycine dihydrochlorid 37,5mg ($\pm$ 1,5 tablets; 25mg $\pm$ 20.93mg hydroxycine)
 - ketotifen fumarate (HC 20-511 Sandoz) 1.38mg ($\pm$ 1 capsule)
- H1-antihistamines 2nd generation:
 - acrivastin 8mg TID
 - bilastine 20mg QD ($\pm$ 1 tablet)
 - cetirizine dihydrochlorid 10mg QD ($\pm$ 1 tablet $\pm$ 8.42mg cetirizine)/ 10mg sirup QD (1ml sirup $\pm$ 1mg cetirizine-2HCl)
 - desloratadine 5mg QD ($\pm$ 1 tablet)
 - ebastine 10mg QD ($\pm$ 1 tablet)
 - emedastine 2mg BID ($\pm$ 1 drop BID; 1ml solution $\pm$ 0.5mg emedastine [0.05%] as difumarate [0.884mg/1ml emedastine difumarate])
 - fexofenadine 180mg QD ($\pm$ 1 tablet)
 - levocetirizine dihydrochlorid 5mg QD ($\pm$ 1 tablet $\pm$ 4.2mg levocetirizine)
 - loratadine 10mg QD ($\pm$ 1 tablet)
 - mizolastine 10mg QD ($\pm$ 1 tablet)
 - rupatadine 10mg QD ($\pm$ 1 tablet $\pm$ 12.79mg rupatadine fumarate)
- doxepine 50mg QD ($\pm$ 5 tablets; 1 tablet $\pm$ 11.31mg rupatadine fumarate)
- omalizumab 150mg and 300mg per month (100mg omalizumab $\pm$ 1ml solution in syringe)
- TNF-alpha inhibitors: adalimumab, certolizumab pegol, etanercept, golimumab, infliximab
- anakinra (100mg) in 0.67ml (150 mg/ml) syringe
- rituximab (50ml contain 500mg rituximab [CHO-cells])
- intravenous immunoglobulins (IVIg)
- methotrexate
- phototherapy: UVB, narrow band-UVB, PUVA
- cyclosporine
- tacrolimus
- montelukast 10mg ($\pm$ 10.38mg montelukast natrium)
- dapsone
- sulfasalazine
- hydroxychloroquine
- colchicine
- autologous whole blood (AWB)/ autologous serum/ autohemotherapy
- heparin
- pseudoallergen-free diets (has to be defined as such in the trial)
- oral corticosteroids (prednisone, prednisolone, methylprednisolone, triamcinolone, betamethasone, dexamethasone)
- dupilumab
- benralizumab
- remibrutinib
- tezepelumab
- mepolizumab

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Comparisons:

- 2nd generation H1-AH versus placebo or versus 1st generation H1-AH
- 2nd generation H1-AH low dose versus high dose (up to 4-fold)
- H1- AH versus other therapies or versus H1-AH combined with other therapies or other therapies versus each other (other therapies refers to those listed above)

Outcomes:

- at least one efficacy outcome had to be reported in a study for the study to be included (see above)
- for the comparison 1st gen AH vs 2nd gen AH details in regards to adverse events (AEs) will be extracted and no efficacy outcome is necessary as inclusion condition
- outcome of special interest in regards to sleep for the comparison 2nd generation H1-AH versus 2nd generation H1-AH regularly versus as needed and up dosing
- outcome assessment: 1-2 weeks or 3-12 weeks after the treatment was started

Study type:

- prospective controlled clinical trial (defined as a clinical study that includes a comparison group) or randomized controlled trial

BOX 2: EXCLUSION CRITERIA

- acute urticaria
- healthy volunteers with induced wheals
- urticaria pigmentosa
- food-induced allergic reaction, for example, shrimp allergy
- hereditary angioneurotic edema/ hereditary angioedema (HAE)
- contact urticaria
- diets other than as defined as pseudoallergene diet
- studies reporting outcomes at a follow-up time of more than 12 weeks only
- outcome assessment after a treatment duration shorter than 1 week
- comparisons of same medication in different treatment regime (for example verum A up dosing every week versus verum B up dosing every week,) or different applications (for example, tablet versus capsule)

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SCREENING AND DATA EXTRACTION

At least two researchers (RH, CZ, and/or AP) independently screened the titles and abstracts of all hits for eligibility. In cases where no abstract was available and the title did not give an obvious reason for exclusion, we obtained the full-text publication. The two researchers subsequently screened the full-text publications of the included titles and abstracts for eligibility. In some cases, only abstracts were available; we included these if they met our eligibility criteria.

Data were then extracted from the included publications by the researchers independently of each other using a standardized data extraction form in MS Excel. These were subsequently compared and differences of opinion were resolved by discussion. The items listed in Table 4 were extracted if available in the pre-defined format. Data were transformed whenever appropriate (see below). We used Engauge Digitizer Version 4.7 to extract data points from images of graphs.

TABLE 4: ITEMS FOR DATA EXTRACTION

Study characteristics and baseline data	
First author and year	First author and year of print publication
Intervention	Latin abbreviation for treatment regimen; duration of treatment as stated in publication; PBO for matched placebo and 'nothing' for no medication
Randomized or assigned patients	n (number of patients per arm)
Study design	Type of RCT or CCT, multi-centre (MC) or single-centre (SC)
Inclusion criteria disease	CIU, CSU, CU or CIndU type; extraction of full inclusion criteria from study
Inclusion criteria age	Years (as stated)
Special patient population	No; children (age), pregnant or lactating women
Washout	Duration and medication
Concomitant treatment	As stated in publication
Age at baseline	Mean±SD, median (IQR), or range (as reported in publication)
Gender distribution at baseline (female)	% (rounded off to whole numbers)
Outcomes: efficacy and HRQL data are extracted for week 1-2 and week 3 – 12	
Follow-up point in time	As stated in publication
Definition of outcome (scoring)	As stated in publication - <i>must be investigator assessed</i>
Matched outcome	State score that was matched with 'complete suppression'
Patients with complete suppression	n/N
Matched outcome	State score that was matched with 'good' or 'excellent'
Patients with at least 'good' or 'excellent' response	n/N (includes n of complete suppression)
Follow-up point in time	As stated in publication
Definition of efficacy score	As stated in publication
Mean change (SD)	Mean±SD and n / <i>make note of who assessed</i>
Follow-up point in time	As stated in publication
UAS or UAS7	state which one: UAS or UAS7 / <i>make note of who assessed it</i>
Patients with ≤ 6 points	n/N
Follow-up point in time	As stated in publication
Definition of HRQL outcome	As stated in publication
Mean change (SD)	Mean±SD and n
Patients with ≥50% improvement in QoL	n/N
Outcomes: Adverse events and Relapse	
Withdrawal/drop out due to adverse event	n/N
Point in time of adverse event	As stated in publication
Patients with at least 1 adverse event	n/N

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Adverse Events

Number of patients with somnolence, fatigue, drowsiness, tiredness, dizziness *for studies comparing 1st vs. 2nd gen AH only (preferable 'patient-assessed')*

Definition of relapse

Definition of relapse at time x (up to max. 6 months)

Proportion of patients relapsing at time x

n/N

Notes: CCT: controlled clinical trial; CindU: chronic inducible urticaria; CIU: chronic idiopathic urticaria; CSU: chronic spontaneous urticaria; CU: chronic urticaria; IQR: interquartile range; QoL: quality of life; RCT: randomised controlled trial; SD: standard deviation; UAS: urticaria activity score; UAS7: seven-day urticaria activity score

STATISTICAL ANALYSIS

This section is, in large part, identical to that in the previous Methods and Evidence Report²

We calculated risk ratios and mean differences with the corresponding 95% confidence intervals using Review Manager 5.4.⁵ Each comparison and outcome were entered into Review Manager separately, and subgroups for each point in time of evaluation were created. We included several multi-arm studies where the comparator arm was split in case of multiple comparisons to avoid counting participants more than once (only when data were later pooled). The methods offered by Review Manager are not ideal for analysing rare events (e.g., number of/proportion of patients, who experiences an adverse event). A zero-cell correction is applied or an estimation is not possible when events are zero in both groups; other statistical methods offer options, but are advanced and present own drawbacks.⁶⁻⁸ Hence, we decided to calculate the risk difference instead of the risk ratio in some cases.

Decisions on appropriateness of pooling the data were made taking the PICO and the key question into consideration. We choose the Mantel-Haentzel approach using a random-effects model because the difference between the studies suggested that no common effect was assessed (DerSimonian-Laird).⁹ The decision was made to pool data if heterogeneity was $I^2 \leq 80\%$. In cases where $I^2 \geq 40\%$, we downgraded during the assessment of the quality of evidence (GRADE – inconsistency criteria).

We pooled data across time points: week 1 and 2, week 3 and 4 and across week 5 and 6. Data were not pooled across 8 and 12 weeks or when the dosage changed between two time points. If multiple time points had been reported, we preferred the earliest time point in each time bracket.

Due to the different assessment scales used, we calculated an SMD where this was more appropriate.

DATA TRANSFORMATION

We performed a variety of data transformations because the data reported in the included publications were not always in a format suitable for meta-analysis.

$$SD_{E, \text{change}} = \sqrt{SD_{E, \text{baseline}}^2 + SD_{E, \text{final}}^2 - (2 \times \text{Corr}_E \times SD_{E, \text{baseline}} \times SD_{E, \text{final}})}$$

$$\text{Corr}_E = \frac{SD_{E, \text{baseline}}^2 + SD_{E, \text{final}}^2 - SD_{E, \text{change}}^2}{2 \times SD_{E, \text{baseline}} \times SD_{E, \text{final}}}$$

In order to calculate summary measures for continuous outcomes, a measure of dispersion, i.e. the standard error or the standard deviation (SD) had to be available. For continuous outcomes the absolute mean change in a score from baseline could be calculated where baseline and final data were provided.

The corresponding standard deviation could only be calculated using the formula below if we were able to use data from another publication and calculate a correlation coefficient assuming that the intervention did not change the variability of the outcome measures, as suggested by Cochrane.¹⁰

Otherwise missing standard deviations for mean changes were calculated based on the confidence interval and the standard error. If only the baseline mean value $\pm$ SD and the end mean value without SD (i.e., was digitised from a chart) was available or the final mean $\pm$ SD but no SD for the mean change was reported or calculable, no effect measure could be calculated. Concerning dichotomous efficacy outcomes, we calculated a non-responder-imputation-based ITT to harmonize the data pool.

$$SE = (\text{upper limit CI} - \text{lower limit CI}) / 3.92$$

$$SD = SE \times \sqrt{N}$$

Mean change was always preferred, but if not available or the above calculations were not possible, we pooled the final mean and mean change.

CRITICAL APPRAISAL OF EVIDENCE

RISK OF BIAS ASSESSMENT

The data extraction sheet also contained the categories of the Cochrane Risk of Bias Assessment Tool,¹¹ which we used to assess *sequence generation*, *allocation concealment* and *other sources of bias* at the study level, and *blinding of patients and personnel* and *blinding of outcome assessment* at the outcome level. For the specific decision-making criteria used to make the assessments, please refer to the previous Methods and Evidence Report.² We used the ROBINS – I tool for non-randomized clinical controlled trials.¹²

GRADE ASSESSMENT OF THE QUALITY OF EVIDENCE

The GRADE approach was used to appraise the quality of evidence and develop evidence-to-decision frameworks.¹³ We created GRADE evidence profiles for each comparison. During this process, the following five criteria were used to rate each outcome as *not serious*, *serious* (downgraded by 1 level) or *very serious* (downgraded by 2 levels). Randomized, controlled trials (RCT) start with the highest rating (not serious). A summary of the criteria influencing the quality and the different quality levels are displayed in Table 5 (adapted from Bashem et al. 2001¹⁴). Each criterion that may decrease the quality rating is described in detail below.

TABLE 5: SUMMARY OF THE GRADE APPROACH TO ASSESSING THE QUALITY OF EVIDENCE BY OUTCOME IN RANDOMISED CONTROLLED TRIALS¹⁴

Initial quality of the body of evidence	Criteria that may decrease the quality rating	Criteria that may increase the quality rating	Quality of the body of evidence	
High	– Risk of bias – Inconsistency	– Large effect – Dose response	High (++++)	We are very confident that the true effect lies close to that of the estimate of effect.

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– Indirectness – Imprecision – Publication bias	– Residual confounding	Moderate (+++)	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
		Low (++)	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
		Very low (+)	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

1. *Risk of bias*: The Cochrane Risk of Bias Assessment tool was used. We downgraded if several risk of bias items were deemed unclear and/or high. Where more than one study had been included in a meta-analysis, we looked at the weights assigned in the meta-analysis to help determine the overall risk of bias.

2. *Inconsistency*: If only one study was available, we could not assess inconsistency. No default option for this case is available; hence, we rated inconsistency as *not serious*. If more than one study was included, we downgraded to *serious* if statistical heterogeneity was detected as $I^2 \geq 40\%$ and to *very serious* if $I^2 \geq 70\%$.

3. *Indirectness*: Only if the population and/or intervention specified in the key question differed from the population and/or intervention in the studies included did we downgrade to *serious*. For example, if a study included non-responders to different doses of H1-AH but the PICO question had specified for the population to be non-responder to high doses of H1-AH did we downgrade.

4. *Imprecision*: Imprecision was rated as *serious* if the confidence interval was very wide (for example, 0.06 to 15.14 or 2.05 to 97.04). In addition, the boundaries of the calculated confidence intervals were assessed. The GRADE approach postulates for the minimal clinically important difference (MID) thresholds to be larger than 25% benefit (1.25) and 25% harm (0.75).¹⁴ If the confidence interval crossed the MID threshold this represents uncertainty in regards to clinical importance. If one or both MID thresholds were crossed, we downgraded to *serious*. If only the line of no effect was crossed but no MID threshold, we did not downgrade because the result is precise.

For continuous outcomes, we based our assessment on MID thresholds that are anchor-based and available in the peer-reviewed literature. For the Dermatology Quality of Life Index with a possible range of scores from 0 to 30 and the Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL) with a possible range of scores from 0 to 100, the MID threshold used was 3 (Shikier et al. 2005 suggested 2.2 to 3.2 for the DLQI; ¹⁵ Baiardini et al. suggested 3 for the CU-Q2oL). For the Urticaria Activity Score 7 (UAS7) Mathias et al. 2012 had suggested an MID range from 9.5 to 10.5, we used 10.¹⁶ In cases where we

calculated the risk difference for rare events (for example for AEs), we used a 2% as the MID. When we used the SMD, we used - 0.2 / 0.2 (as small effect, see Cohen).

Where no anchor-based MIDs were available, we used distribution-based MIDs, namely $\frac{1}{2}$ the SD.¹⁷ We did not downgrade the quality rating for imprecision in the case of zero events.

5. Publication bias: Due to the small number of studies whose data were pooled for most comparisons, we were unable to assess publication bias, for example, using a funnel plot and rated this form of bias as ‘undetected’.

Just as we used each PICO question to create a GRADE evidence profile (or set of such profiles), so too did we use each GRADE evidence profile to develop an Evidence-to-Decision (EtD) framework. These aimed to help the members of the expert panel (a) make an overall judgement regarding the size of the desirable and undesirable effects of specific comparisons and the balance between the two, (b) summarize the overall quality of the evidence, and (c), in doing so, develop the evidence- and consensus-based guideline recommendations and accompanying background texts.

RESULTS OF THE EVIDENCE UPDATE

The literature search on February 9, 2024 identified 1946 records. The removal of duplicates left 1513 records for the title/abstract screening, of which 1256 were excluded. This left 258 records to be assessed as full texts for eligibility, of which 246 were excluded. A list of excluded full-text publications with reasons for exclusion can be found in Appendix 2. A total of 12 records were ultimately included in the evidence-based review. These comprised (a) 10 new studies reporting data on treatments for CSU and (b) two new studies reporting data on treatments for CINDU. A breakdown of this process can be seen in the study selection flowchart in

Figure 1. Additionally, in the EtD frameworks, an asterisk (*) after an author-year reference or a particular outcome indicates where new data were identified or added to existing data as part of the previous update of the guideline.

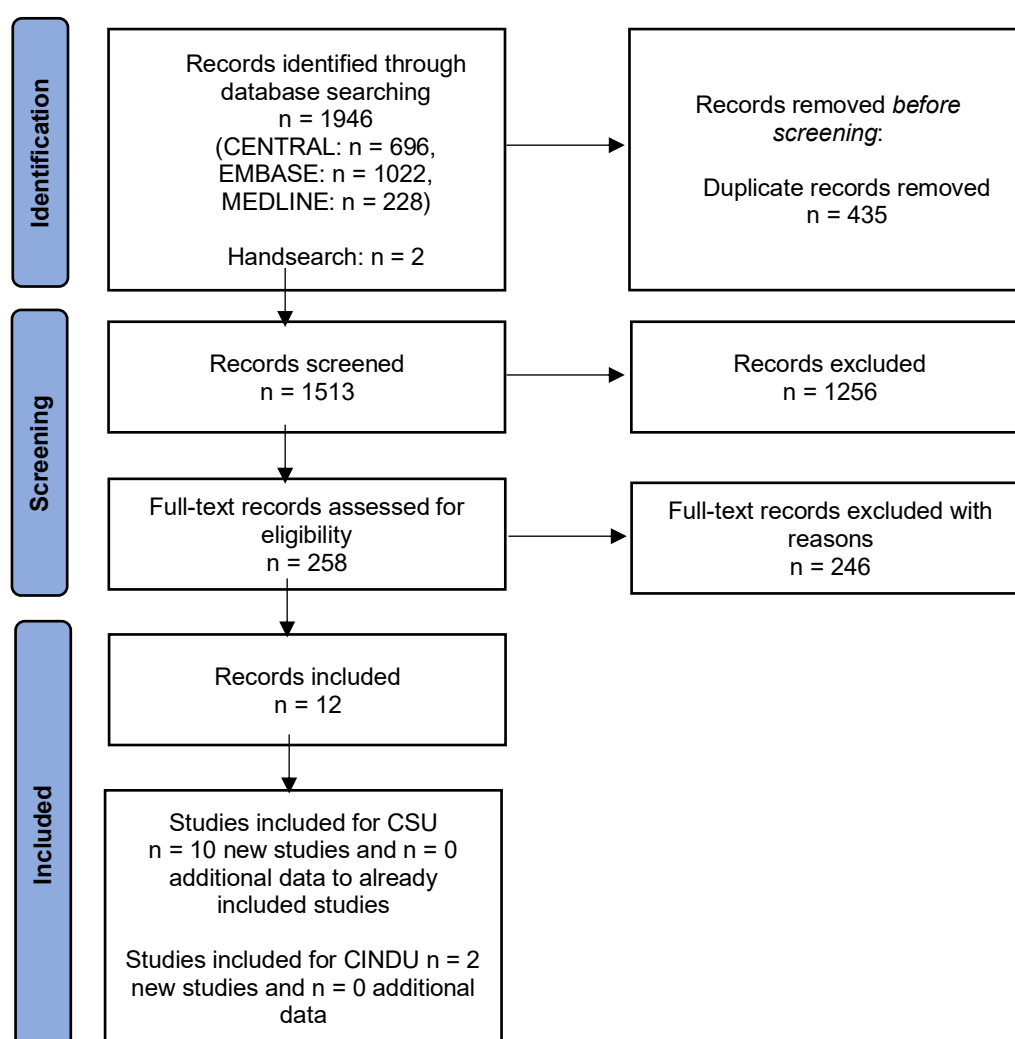


FIGURE 1. STUDY SELECTION FLOWCHART

We created a total of 12 new or updated GRADE evidence profiles and 12 new or updated EtD frameworks. A summary of the evidence is given in the Evidence Report, which is available on the EDF website (<https://www.guidelines.edf.one/edf-guidelines-and-consensus-statements>).

DEVELOPING RECOMMENDATIONS AND THE CONSENSUS PROCESS

When developing the guideline recommendations, the expert panel always used the standardized wording suggested by the GRADE Working Group and in accordance with the EuroGuiDerm Manual (see Table 6).^{4 18}

TABLE 6: WORDING OF RECOMMENDATIONS¹⁹⁻²²

Strength	Wording	Symbols	Implications
Strong recommendation for the use of an intervention	'We recommend . . .'	↑↑	We believe that all or almost all informed people would make a choice in favor of using this intervention. Clinicians will not have to spend as much time on the process of decision-making with the patient and may devote that time instead to overcoming barriers to implementation and adherence. In most clinical situations, the recommendation can be adopted as a policy.
Weak recommendation for the use of an intervention	'We suggest . . .'	↑	We believe that most informed people would make a choice in favor of using this intervention, but a substantial number would not. Clinicians and other health care providers will need to devote more time to the process of shared decision-making. Policy makers will have to involve many stakeholders and policy making will require substantial debate.
No recommendation with respect to an intervention	'We cannot make a recommendation with respect to . . .'	0	Currently, a recommendation in favor of or against using this intervention cannot be made due to certain circumstances (for example, unclear or balanced benefit-risk ratio, no data available).
Weak recommendation against the use of an intervention	'We suggest against . . .'	↓	We believe that most informed people would make a choice against using this intervention, but a substantial number would not.
Strong recommendation against the use of an intervention	'We recommend against . . .'	↓↓	We believe that all or almost all informed people would make a choice against using this intervention. This recommendation can be adopted as a policy in most clinical situations.

At the beginning of the guideline development process, the guideline coordinators (Marcus Maurer and Torsten Zuberbier) divided the expert panel into two groups of roughly equal size. One group was chiefly responsible for the guideline sections on classification and diagnosis, which were developed based on expert consensus, and the other group was chiefly responsible for the guideline sections on disease

management, most of which were developed based on the results of our systematic search of the literature and meta-analysis of data from the included studies.

Members of the classification and diagnosis group were instructed to write draft recommendations based on their clinical expertise and expert consensus within group while drawing as necessary upon relevant literature. In turn, members of the disease management group, were instructed to write draft recommendations based on the GRADE profiles and EtD frameworks we supplied to them as part of our Evidence Report, and on their clinical expertise within the subgroup. The guideline coordinators helped coordinate this process.

We conducted an online survey among all the members of the expert panel, in the weeks before the consensus conference on December 6, 2024 in order to (a) familiarise the group with all of the draft recommendations, (b) gather feedback from the group on these recommendations and (c) subsequently use this feedback to modify the recommendations or to draft alternatives to them to be presented and voted upon during the consensus conference on December 6, 2024.

The online survey focused on both the diagnosis and classification as well as the management section of the guideline. The survey began on 12 November 2024 and lasted for two weeks.

Both surveys were conducted using LimeSurvey and were structured as follows: the participants were shown each of the draft recommendations. Participants were given the option to agree with draft recommendation, to agree with the draft recommendation but to comment on it, or to disagree with the draft recommendation and to comment on it and provide an alternative draft recommendation. In preparation for the online survey the rationale for the respective recommendation for each evidence-based question was presented to the guideline group via the evidence report.

All members of the expert panel without personal financial conflicts of interest were eligible for voting. Comments and suggestions for changes to the recommendations were considered irrespective of conflicts of interest. A total of 127 of the 207 members of the expert panel (61.35%) participated in the survey. Agreement rates were generally high (above 80%), and several suggestions for editorial changes to the wording of recommendations were taken into account.

CONSENSUS CONFERENCE (DECEMBER 6, 2024)

Consensus conference participants were a large international group of experts consisting of (a) the expert panel and (b) a much broader group of participants, who had registered for the conference out of interest in the subject and were qualified as physicians regularly involved in treating patients with urticaria or had been involved in basic or clinical research in the field. The aim of including this broader group was to help to ensure the regional implementability of the guideline, both by drawing upon the group's expertise and by asking them to serve as ambassadors for the guideline and its implementation.

Before the consensus conference, we incorporated the results of the online pre-voting into the draft recommendations, and made the evidence-to-decision frameworks available to all participants registered to take part in the consensus conference on December 6, 2024. Those who wanted to vote during the conference also had to submit the conflict of interest declaration. Personal financial conflicts of interest were categorized as either relevant for pharmacological treatment or

diagnostics/classification of urticaria. Everyone except for those employed at a pharmaceutical company and those with personal financial conflicts of interest were eligible to access the live polls. Eligible voters received a unique code granting access to the live polls for the sections they were permitted to vote on.

Ricardo N. Werner moderated the conference and used the nominal group technique to facilitate the consensus process. First, each draft recommendation and the justification or evidence was presented, discussed one by one, which was followed by final consensus voting. As this was a hybrid conference, we used the Vevox© tool to create live voting polls. Those participants, who declared to work for industry and those with personal financial conflicts of interests, did not receive the access code.

In the guideline itself, the strength of the consensus reached for each recommendation is reported as shown in Table 7.

TABLE 7: STRENGTH OF CONSENSUS ACCORDING TO EUROGUIDERM GUIDELINE MANUAL⁴

Strong consensus	Agreement of >95% participants
Consensus	Agreement of >75-95% participants
Agreement of the majority	Agreement of >50-75% participants

Each recommendation in the guideline is formatted as shown in Box 1-Box 3. At the top of each box, the question of interest is given (e.g., “Should we ... in chronic urticaria?”). In the row below the question of interest, the recommendation is spelled out in full using the standardized wording and symbols shown in

Table 6. In Box 1, for example, we can see that a strong recommendation is being made (i.e., “We recommend...” and “↑↑” in dark green). Additionally, we can see, based on the information given on the right-hand side of this same row, that the eligible participants in the consensus conference agreed upon this recommendation and its wording with strong consensus (>95% agreement) and that the recommendation is based on expert consensus. If the recommendation is based, additionally, on evidence from a systematic review of the literature, the phrase used here will read “Evidence- and consensus-based (see Evidence Report)” instead of “Expert consensus”.

If there are multiple recommendations that address the same question of interest and each of these recommendations was voted upon separately, these can be grouped together as shown in Box 2. In this case, the strength of consensus and the evidence base are given for each recommendation separately.

In Box 3, we also see two recommendations instead of one. However, in this case, because these were voted on jointly in the consensus conference, the information on the strength of consensus and the evidence base are shown only once and apply to both recommendations.

BOX 1: FORMAT FOR INDIVIDUAL GUIDELINE RECOMMENDATIONS, INCLUDING STRENGTH OF CONSENSUS AND EVIDENCE BASE

Should we ... in chronic urticaria?

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We recommend that ...	↑↑	Strong consensus ¹ Expert consensus
¹ >95% agreement		

BOX 2: FORMAT FOR MULTIPLE GUIDELINE RECOMMENDATIONS VOTED UPON SEPARATELY, INCLUDING STRENGTH OF CONSENSUS AND EVIDENCE BASE FOR EACH

Should we ... in chronic urticaria?		
We recommend that ...	↑↑	Strong consensus ¹ Expert consensus
¹ >95% agreement		
We suggest that ...	↑	Strong consensus ¹ Expert consensus
¹ >95% agreement		

BOX 3: FORMAT FOR MULTIPLE GUIDELINE RECOMMENDATIONS VOTED ON JOINTLY, INCLUDING STRENGTH OF CONSENSUS AND EVIDENCE BASE

Should we ... in chronic urticaria?		
We recommend that ...	↑↑	Strong consensus ¹
We recommend using ...		Expert consensus
¹ >95% agreement		

DEVELOPING TEXTS

Following the consensus conference, the guideline coordinators Martin Metz and Torsten Zuberbier amended the text from the 2021 guideline in line with points generated by the expert panel during the pre-conference online voting as well as the in line with points discussed during the consensus conference. The draft was reviewed by the group (see below).

INTERNAL AND EXTERNAL REVIEW

The draft guideline was sent to the expert group for internal review on February 05, 2025, and the group had two weeks, until February 19, 2025, to provide their written feedback on the document. All comments received were reviewed and implemented by the guideline coordinators (Torsten Zuberbier and Martin Metz). The resulting document was subsequently sent to all endorsing societies, and to involve a more general audience, to all members of the EDF for external review from 08. 07. 2025 to 19. 08. 2025. As with the internal review, all comments were reviewed and rated for relevance by the guideline coordinators (Martin Metz and Torsten Zuberbier). The comments based on newly published evidence on safety or inefficacy were incorporated in the final text and were marked as external comments.

DISSEMINATION AND IMPLEMENTATION

The dissemination and implementation activities pursued in related to the present guideline are given below in Table 8.

EVALUATION METHODS

Monitoring and evaluation of the implementation of the guideline will take place at the national level.

- Change in practice performance
- Change in health outcomes
- Change in end-user knowledge and understanding

RESOURCE IMPLICATIONS

Because this is an international guideline, the resource implications of the recommendations therein will vary from jurisdiction to jurisdiction. It was agreed during the consensus conference that panel members would feed back any relevant information on this point.

RESEARCH PRIORITIES

The expert group identified a range of need for further research. The list below is identical to the list given in Table 12 of the main guideline document²:

- Global epidemiology, in adults and children
- The socio-economic consequences, particularly in developing countries
- Identification of mast cell/basophil activating factors
- Identification of new histological markers
- Identification of serum biomarkers of urticarial activity/mast cell activation
- Clarification of the role of coagulation/coagulation factors in CSU
- Development of commercially available *in vitro* tests for detecting serum auto-antibodies for anti-IgE and anti-FcεRI
- Further evaluation of IgE- and IgG auto-antibodies
- Clarification of associated psychiatric /psychosomatic diseases and their impact
- Pathomechanisms in antihistamine-resistant urticaria/angioedema
- Double blind controlled trials comparing different modern 2nd generation H₁-antihistamines in higher doses in CSU and different subtypes of urticaria
- Safety profile of available treatments, long term pharmacosurveillance
- Multicenter studies on the possible effect of anticoagulants (oral and heparin derivatives) on CSU
- Controlled multicenter trials on the possible effect of add-on of H₂-antihistamines, montelukast, sulfones (dapsone/sulfasalazine), methotrexate, azathioprine, and
- Define and achieve consensus on key concepts such as complete control, remission, relapse or disease modification
- Validation of clinical and serum biomarkers that predict therapeutic response to antihistamines, omalizumab, ciclosporin, and future CU drugs
- Development of better treatment options for patients with difficult-to-treat endotypes, including disease-modifying treatments
- Investigation of molecular and cellular factors associated with urticaria remission
- Trials and licensing of 2nd generation H₁-antihistamines for the treatment of children below 6 months of age

STRENGTHS AND LIMITATIONS

This section is, in large part, identical to that in the previous Methods and Evidence Reports^{23 24}

The strength of the body of evidence presented lies within the application of rigorous and systematic methods as recommended by Cochrane and the GRADE working group, which we describe in detail here. We also used Evidence to Decisions Frameworks to include the balance of potentially desirable and undesirable effects as well as to raise awareness about the feasibility, costs, equity and acceptability of the intervention. These barriers to implementation need to be considered within the national or local context.

The evidence identified regarding the treatment of urticaria is very diverse and many studies report different outcomes at different time points. The reader should be aware of the issue of multiplicity, although we specified outcomes and time points a priori in the protocol. There were no protocol amendments or deviations from the protocol.

Concerning statistical limitations, for different comparisons we did pool two trials although the detection of heterogeneity using the I^2 statistics is suboptimal. It is also worth mentioning that the UAS7 is scored in two different ways. When pooling data, we did not differentiate between these two systems. However, Karsten Weller (expert, Weller et al [unpublished data]) found that these two scoring systems are very similar. With regard to the assessment of various outcomes, some trials did not report whether the outcome was patient or physician-assessed. Each unclear case was debated within the review team and a pragmatic approach was chosen when handling the data.

Due to resource restrictions we neither searched for further evidence by hand nor did we search grey literature repositories or trial registers. However, a large number of experts were involved in the guideline development process, and no missing or ongoing trials were evident. The review protocol specified that each primary study had to report the necessary data to be able to calculate effect measures. Reporting was often suboptimal and studies had to be excluded. We did not qualitatively report on these studies, and this choice may have introduced reporting bias.

UPDATE AND METHODS

The expert panel will decide if and when an update is necessary, at the latest five years from the date of publication of the 2024/25 guideline.

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TABLE 8: DISSEMINATION PLAN

Audience	Responsible Subcommittee member(s)	Communication and/or implementation tools to be used	Time at which they are to be developed, piloted or to take place	Is EuroGuiDerm support needed, and if yes what kind of support?
Dermatologists, allergologists	Torsten Zuberbier, Ricardo N. Werner	Full guideline & methods report & flow charts – EDF website	After completion of external review	Yes, RW/MD editorial support
Dermatologists, allergologists, researchers	Torsten Zuberbier, Ricardo N. Werner	Journal publication	The draft version will be submitted to an academic journal at the same time as it is submitted for external review	Yes, RW/MD editorial support
Dermatologists, allergologists	Torsten Zuberbier	Implementation slides	At the same time as the guideline draft	–
Physicians, researchers, patients, public	Ricardo N. Werner	EuroGuiDerm Newsletter	After completion of external review	Ricardo N. Werner

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APPENDIX 1: SEARCH STRATEGIES

Date: 02.09.2024

Database: Ovid MEDLINE(R) ALL 1946 to February 09, 2024

Hits: 228

1. exp Urticaria/
2. "urticaria*".ab,kf,ti.
3. hives.ab,kf,ti.
4. w?eals.ab,kf,ti.
5. "dermatographi*".ab,kf,ti.
6. ("factiti*" adj3 urticaria*).ab,kf,ti.
7. ((cold or heat or pressure or solar) adj3 urticaria*).ab,kf,ti.
8. (vibratory adj3 angio?edema).ab,kf,ti.
9. ((cholinergic or contact) adj3 urticaria*).ab,kf,ti.
10. ((aquagenic or (water adj3 induc*)) adj3 urticaria*).ab,kf,ti.
11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12. randomized controlled trial.pt.
13. controlled clinical trial.pt.
14. randomized.ab.
15. placebo.ab.
16. clinical trials as topic.sh.
17. randomly.ab.
18. trial.ti.
19. or/12-18
20. exp animals/ not humans.sh.
21. 19 not 20
22. 11 and 21
23. ("202005*" or "202006*" or "202007*" or "202008*" or "202009*" or "202010*" or "202011*" or "202012*" or "2021*" or "2022*" or "2023*" or "2024*").dt.
24. 22 and 23

Date: 02.09.2024

Database: Embase Classic+Embase 1947 to 2024 Feb 09

Hits: 1022

1. exp *Urticaria/
2. "urticaria*".ab,kw,ti.
3. hives.ab,kw,ti.
4. w?eals.ab,kw,ti.
5. "dermatographi*".ab,kw,ti.
6. ("factiti*" adj3 urticaria*).ab,kw,ti.
7. ((cold or heat or pressure or solar) adj3 urticaria*).ab,kw,ti.
8. (vibratory adj3 angio?edema).ab,kw,ti.
9. ((cholinergic or contact) adj3 urticaria*).ab,kw,ti.
10. ((aquagenic or (water adj3 induc*)) adj3 urticaria*).ab,kw,ti.
11. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
12. Randomized controlled trial/
13. Controlled clinical study/
14. random\$.ti,ab.
15. randomization/
16. intermethod comparison/
17. placebo.ti,ab.
18. (compare or compared or comparison).ti.
19. ((evaluated or evaluate or evaluating or assessed or assess) and (compare or compared or comparing or comparison)).ab.
20. (open adj label).ti,ab.
21. ((double or single or doubly or singly) adj (blind or blinded or blindly)).ti,ab.
22. double blind procedure/
23. parallel group\$1.ti,ab.
24. (crossover or cross over).ti,ab.

25. ((assign\$ or match or matched or allocation) adj5 (alternate or group\$1 or intervention\$1 or patient\$1 or subject\$1 or participant\$1)).ti,ab.
26. (assigned or allocated).ti,ab.
27. (controlled adj7 (study or design or trial)).ti,ab.
28. (volunteer or volunteers).ti,ab.
29. human experiment/
30. trial.ti.
31. or/12-30
32. random\$ adj sampl\$ adj7 ("cross section\$" or questionnaire\$1 or survey\$ or database\$1).ti,ab. not (comparative study/ or controlled study/ or randomi?ed controlled.ti,ab. or randomly assigned.ti,ab.)
33. Cross-sectional study/ not (randomized controlled trial/ or controlled clinical study/ or controlled study/ or randomi?ed controlled.ti,ab. or control group\$1.ti,ab.)
34. (((case adj control\$) and random\$) not randomi?ed controlled).ti,ab.
35. (Systematic review not (trial or study)).ti.
36. (nonrandom\$ not random\$).ti,ab.
37. "Random field\$".ti,ab.
38. (random cluster adj3 sampl\$).ti,ab.
39. (review.ab. and review.pt.) not trial.ti.
40. "we searched".ab. and (review.ti. or review.pt.)
41. "update review".ab.
42. (databases adj4 searched).ab.
43. (rat or rats or mouse or mice or swine or porcine or murine or sheep or lambs or pigs or piglets or rabbit or rabbits or cat or cats or dog or dogs or cattle or bovine or monkey or monkeys or trout or marmoset\$1).ti. and animal experiment/
44. Animal experiment/ not (human experiment/ or human/)
45. or/32-44
46. 31 not 45
47. 11 and 46
48. ("202005*" or "202006*" or "202007*" or "202008*" or "202009*" or "202010*" or "202011*" or "202012*" or "2021*" or "2022*" or "2023*" or "2024*").dc.

49. 47 and 48

Date: 02.09.2024

Database: Cochrane Central Register of Controlled Trials (CENTRAL)

Search strategy:

Hits: 696

ID	Search
#1	urticaria*:ti,ab,kw (Word variations have been searched)
#2	MeSH descriptor: [Urticaria] explode all trees
#3	hives:ti,ab,kw (Word variations have been searched)
#4	wheals:ti,ab,kw (Word variations have been searched)
#5	weals:ti,ab,kw (Word variations have been searched)
#6	dermatographi*:ti,ab,kw (Word variations have been searched)
#7	factiti* near/3 urticaria*:ti,ab,kw (Word variations have been searched)
#8	(cold or heat or pressure or solar) near/3 urticaria*:ti,ab,kw (Word variations have been searched)
#9	vibratory near/3 angioedema:ti,ab,kw (Word variations have been searched)
#10	((cholinergic or contact) near/3 urticaria*):ti,ab,kw (Word variations have been searched)
#11	((aquagenic or (water near/3 induc*)) near/3 urticaria*):ti,ab,kw (Word variations have been searched)
#12	#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11

Limit #12 to Publication Year from 2020 to 2024 and Cochrane Library publication date from May 2020 to Feb 2024

APPENDIX 2: LIST OF EXCLUDED FULL-TEXT PUBLICATIONS

Author	Title	Year	Reasons for exclusion	Comments
Alen Coutinho, I. et al.	Clinical and analytical characterization of chronic urticaria adult patients-a one-year study from a portuguese tertiary hospital	2020	Wrong S	Retrospective study
Anonymou s	Corrigendum: An open-label, proof-of-concept study of lrentelimab for antihistamine-resistant chronic spontaneous and inducible urticaria (The Journal of Allergy and Clinical Immunology (2022) 149(5) (1683-1690.e7), (S0091674921026828), (10.1016/j.jaci.2021.12.772))	2022	Other	Corrigendum to PMID: 34954198; original study excluded (no control)
Arga, Mustafa et al.	A randomized controlled trial of adding intravenous corticosteroids to H1 antihistamines in patients with acute urticaria	2021	Other	Commentary on PMID: 32139204; acute urticaria; original study considered in previous GL
Bernstein, J. A. et al.	Why a Complete Response Is the Treatment Aim in Chronic Spontaneous Urticaria	2023	Wrong S	Pooled outcome across treatment arms
Bernstein, J. A. et al.	33586 Complete freedom from chronic spontaneous urticaria signs and symptoms is associated with sleep and dermatology quality-of-life improvements: Data from the phase 2b ligelizumab study	2022	Wrong S	Conference abstract; pooled outcome across treatment arms
Bernstein, J. A. et al.	High rate of complete response with ligelizumab in adults with moderate-to-severe chronic spontaneous urticaria	2021	Other	Conference abstract; no data on omalizumab vs. placebo
Bernstein, J. A. et al.	High rate of complete response with ligelizumab in adults with moderate-to-severe chronic spontaneous urticaria	2021	Other	Duplicate
Bernstein, J. A. et al.	27362 High rate of complete response achieved with ligelizumab in patients with moderate to severe chronic spontaneous urticaria throughout the phase 2b core study	2021	Other	Conference abstract; no data on omalizumab vs. placebo
Bernstein, J. A. et al.	Ligelizumab achieves high rate of complete response in patients with moderate to severe chronic spontaneous urticaria	2020	Other	Conference abstract; no data on omalizumab vs. placebo
Bernstein, J. et al.	Omalizumab reduces the severity of chronic spontaneous urticaria: A real-world survey in the United States	2023	Wrong C	Poster; outcome for comparison aggregated across different interventions (non-omalizumab, no information on group composition)
Bernstein, J. et al.	FREEDOM FROM ITCH AND HIVES IN CHRONIC SPONTANEOUS URTICARIA IS ASSOCIATED WITH IMPROVED QUALITY-OF-LIFE MEASURES	2022	Wrong S	Poster; pooled outcome across treatment arms
Bernstein, J. et al.	FREEDOM FROM ITCH AND HIVES IN CHRONIC SPONTANEOUS URTICARIA IS	2022	Other	Duplicate

	ASSOCIATED WITH IMPROVED QUALITY-OF-LIFE MEASURES			
Bernstein, J. et al.	Ligelizumab Achieves High Rate of Complete Response in Patients with Moderate to Severe Chronic Spontaneous Urticaria	2021	Other	Duplicate
Bernstein, J. et al.	COMPLETE RESPONSE WITH LIGELIZUMAB IN CHRONIC SPONTANEOUS URTICARIA: A COMPOSITE SCORE OF SYMPTOMS AND QUALITY-OF-LIFE	2021	Other	Poster; only percentage of patients (no absolute number) with complete response (composite score) reported
Bernstein, J. et al.	COMPLETE CONTROL OF URTICARIA SYMPTOMS WITH LIGELIZUMAB HELPS NORMALIZE QUALITY OF LIFE	2020		Poster comprising DLQI results (ligelizumab vs placebo); no comparative outcome reported but data sufficient to calculate effect estimate
Bernstein, J. et al.	COMPLETE CONTROL OF URTICARIA SYMPTOMS WITH LIGELIZUMAB HELPS NORMALIZE QUALITY OF LIFE	2020	Other	Duplicate
Bi, Xiao-Dong et al.	Adjunct therapy with probiotics for chronic urticaria in children: randomised placebo-controlled trial	2021	Wrong I	Probiotics
Bisoi, D. et al.	Evaluation of Efficacy and Safety of High Dose Second Generation Non-sedating Antihistamines Levocetirizine and Fexofenadine in Chronic Urticaria- A Prospective, Parallel, Randomized, Single Blind, Comparative Study	2021		Fexofenadine vs levocetirizine; up dosing contingent on responder status and only highest dose analyzed; no numerical outcomes reported
Bogomolov, A. et al.	Safety and clinical efficacy of bilastine in reducing pruritus in patients with chronic spontaneous urticaria	2023	Wrong C	Conference abstract; no control mentioned and outcome expressed in terms of improvement from baseline
Bonnekoh, Hanna et al.	Inhibition of interleukin-1 with rilonacept is not effective in cold urticaria-Results of a randomized, placebo-controlled study	2023	Wrong I	Rilonacept
Carr, W. et al.	REMIBRUTINIB IMPROVES CHRONIC SPONTANEOUS URTICARIA IN PATIENTS IRRESPECTIVE OF CU-INDEX: RESULTS FROM PHASE 2B STUDY	2022		Conference abstract; subgroup analysis contingent on CU-index status; outcome pooled across different doses
Casale, T. et al.	TIME TO CLINICALLY MEANINGFUL RESPONSE TO OMALIZUMAB IN PATIENTS WITH CHRONIC SPONTANEOUS URTICARIA	2022		Poster; outcome from pooled cohorts and only reported in terms of statistical significance (data could potentially be extracted from time series plot); Re-analysis of Asteria I and II (included in previous review)
Chakraborty, D. et al.	47 Bilastine in refractory chronic spontaneous urticaria: disease control and cytokine modulation in an open-label prospective study	2023	Wrong C	Conference abstract; no control
Chen, Q. et al.	070 Levels of plasma total IgE and D-dimer and basophil FcεR1 expression as potential predictors of response to autologous whole blood injection in chronic spontaneous urticaria	2020	Wrong O	Conference abstract; no outcome data other than statement of superiority of treatment under investigation
Chen, Q. et al.	070 Levels of plasma total IgE and D-dimer and basophil	2020	Other	Duplicate

	FcepsilonR1expressionas potential predictors of response to autologous whole blood injection in chronic spontaneous urticaria			
ChiCtr	Double-blind, double dummy, randomized, multicentre, Phase III study to evaluate efficacy and safety of bilastine 20 mg and levocetirizine 5 mg once daily for the treatment of chronic idiopathic urticaria	2023	Other	Trial registry w/out available results
ChiCtr	Efficacy and safety of narrow band ultraviolet B (NB-UVB) in the treatment of cholinergic urticaria	2022	Other	Trial registry w/out available results
ChiCtr	A randomized, double-blind, multi-center exploratory clinical study of desloratadine citrate capsules in the treatment of chronic spontaneous urticaria	2022	Other	Trial registry w/out available results
ChiCtr	Efficacy and mechanism of autologous lymphocytes in the treatment of chronic urticaria	2021	Other	Trial registry w/out available results
Chitnis, T. et al.	Remibrutinib, a Novel Highly Selective and Potent BTKi in Development for MS: Analysis of Safety Data From the Completed Phase 2 Studies in Other Inflammatory Immune-Mediated Diseases	2023	Wrong P	Multiple sclerosis
Ctri	a study on combined benefits of probiotics and desloratadine as compared to desloratadine alone in chronic spontaneous urticaria – An open labelled randomized controlled trial at a tertiary care centre in Central India	2023	Other	Trial registry w/out available results
Ctri	Effect of two Antihistamines in Chronic Urticaria Patients	2023	Other	Trial registry w/out available results
Ctri	Additive effect of histaglobulin in chronic spontaneous urticaria	2023	Other	Trial registry w/out available results
Ctri	In chronic urticaria patients Which drug is better between tab bilastine 20 mg and tab levocetirizine 10 mg	2022	Other	Trial registry w/out available results
Ctri	Comparison of levocetirizine and bilastine for treatment of childhood transient red itchy skin rash	2022	Other	Trial registry w/out available results
Ctri	Comparative study of various antihistamines in the treatment of urticaria	2022	Other	Trial registry w/out available results
Ctri	A comparative study of safety and efficacy of bilastine updosing (40mg) vs combination of bilastine 20mg with levocetirizine 5mg in the treatment of chronic spontaneous urticaria	2022	Other	Trial registry w/out available results
Ctri	A STUDY TO COMPARE THE EFFICACY OF PHOTOTHERAPY WITH THE ORAL DRUG CYCLOSPORINE IN THE TREATMENT OF CHRONIC URTICARIA WHICH IS NON-RESPONSIVE TO TREATMENT	2022	Other	Trial registry w/out available results

Ctri	A Phase 3 study of remibrutinib in the treatment of chronic spontaneous urticaria in adults inadequately controlled by H1- antihistamines	2022	Other	Trial registry w/out available results
Ctri	A Phase 3 study of efficacy and safety of remibrutinib in the treatment of chronic spontaneous urticaria in adults inadequately controlled by H1- antihistamines	2022	Other	Trial registry w/out available results
Ctri	USE OF BILASTINE VS LEVOCETRIZINE FOR ITCHY SKIN RASH	2021	Other	Trial registry w/out available results
Ctri	Effectiveness and safety of up dosing of Bilastine in uncontrolled chronic spontaneous urticaria	2021	Other	Trial registry w/out available results
Ctri	Comparison of bilastine 20mg versus levocetirizine 5mg in chronic urticaria	2021	Other	Trial registry w/out available results
Ctri	Comparing efficacy of different antihistamines in Urticaria	2021	Other	Trial registry w/out available results
Ctri	Clinical Profile And Role Of Dietary Management Of Chronic Spontaneous Urticaria in Children	2021	Other	Trial registry w/out available results
Ctri	comparison of bilastine with cetirizine or fexofenadine in chronic spontaneous urticaria	2020	Other	Trial registry w/out available results
Ctri	To evaluate the effectiveness and safety of non sedating anti allergics for the treatment of Chronic Spontaneous Urticaria	2020	Other	Trial registry w/out available results
Ctri	Evaluation of the effectiveness and tolerability of Bilastine vs Fexofenadine vs Levocetirizine in patients with long term (Chronic)spontaneous urticaria	2020	Other	Trial registry w/out available results
Ctri	Comparison of two drugs cetirizine and bilastine in patients of urticaria	2020	Other	Trial registry w/out available results
Ctri	Camparison of tab bilastine vs tab levovetirizine in treatment of urticaria	2020	Other	Trial registry w/out available results
Dabaghzadeh, Abbas et al.	Probiotics on chronic urticaria: A randomized clinical trial study	2023	Wrong I	Probiotics
Damadoglu, E. et al.	Evaluation of biomarker profile in chronic urticaria to predict disease severity	2023	Wrong S	Case control study; outcome data for omalizumab vs. non-omalizumab only reported in terms of statistical significance
Datta, A. et al.	Subcutaneous autologous serum therapy vs. conventional intramuscular autologous serum therapy in chronic urticaria: A randomised, controlled trial comparing the effectiveness and safety	2020	Wrong I	Conference abstract; comparison between intramuscular and subcutaneous autologous serum therapy; outcome reported only in terms of statistical significance
Datta, A. et al.	Subcutaneous autologous serum therapy vs. conventional intramuscular autologous serum therapy in chronic urticaria: A randomised, controlled trial comparing the effectiveness and safety	2020	Other	Duplicate
Datta, A. et al.	Exploring the safety and effectiveness of subcutaneous autologous serum therapy	2020	Wrong I	comparison between intramuscular and

	versus conventional intramuscular autologous serum therapy in chronic urticaria: An observer-blind, randomized, controlled study			subcutaneous autologous serum therapy (not assessed in previous guideline and only mentioned as potential alternative treatment)
Datta, A. et al.	Exploring the safety and effectiveness of subcutaneous autologous serum therapy versus conventional intramuscular autologous serum therapy in chronic urticaria: An observer-blind, randomized, controlled study	2020	Other	Duplicate
Debbarmann, P. et al.	Therapeutic Round. Autologous Serum Therapy in Chronic Urticaria: a Promising Complement to Antihistamines	2014		Study excluded in previous review: "SD for mean change in UAS not calculable --> no data for RevMan"; only BL and final mean, not CFB reported; no dichotomous outcomes
Dhanya, N. et al.	Histamine 2 blocker potentiates the effects of histamine 1 blocker in suppressing histamine-induced wheal	2008	Wrong P	Healthy subjects
Dickson, Marion C. et al.	Effects of a topical treatment with spleen tyrosine kinase inhibitor in healthy subjects and patients with cold urticaria or chronic spontaneous urticaria: Results of a phase 1a/b randomised double-blind placebo-controlled study	2021	Wrong I	Topical treatment with spleen tyrosine kinase inhibitor GSK2646264
Elhendawy, Mohammed et al.	Positive Effect of Helicobacter pylori Treatment on Outcome of Patients With Chronic Spontaneous Urticaria	2021	Wrong I	Helicobacter pylori eradication
El-Sayed, M. et al.	Comparison of High versus Low dose oral vitamin D supplementation in improving symptoms score and Quality of Life of Patients with Chronic Spontaneous Urticaria	2021	Wrong I	Vitamin D
Ensina, L. F. et al.	Efficacy and Safety of Ligelizumab in Chronic Spontaneous Urticaria: results from the Phase-3 Pivotal Trials	2023	Other	Conference abstract; re-analysis of pooled data from Pearl 1 and 2 studies; outcome reported in terms of least squares estimates (mean change from baseline in UAS7) and percentage of patients with complete response (number of patients per intervention group available); find out whether Pearl studies are reported more comprehensively elsewhere
Euctr Outside EU/EE	Dupilumab for the treatment of chronic spontaneous urticaria in patients who remain symptomatic despite the use of H1 antihistamine and who are naïve to, intolerant of, or incomplete responders to omalizumab	2022	Other	Trial registry w/out available results
Euctr, D. E	Clinical study to investigate whether the new drug (LEO 152020) is efficient and safe for the treatment of a special type of urticaria that is induced by sweating	2021	Other	Trial registry w/out available results

Euctr, D. E	A Phase 3 study of efficacy and safety of remibrutinib in the treatment of chronic spontaneous urticaria in adults inadequately controlled by H1-antihistamines	2021	Other	Trial registry w/out available results
Euctr, D. E	Study to investigate the use of benralizumab in chronic spontaneous urticaria	2020	Other	Trial registry w/out available results
Euctr, D. E	Study for a new medication in Chronic Urticaria	2020	Other	Trial registry w/out available results
Euctr, D. E	Dupilumab for the treatment of chronic inducible cold urticaria in patients who remain symptomatic despite the use of H1-antihistamine	2020	Other	Trial registry w/out available results
Euctr, D. E	A study to evaluate Efficacy and Safety of LY3454738 in Adults with Chronic Spontaneous Urticaria	2019	Other	Trial registry w/out available results
Euctr, E. S	Rilzabrutinib for the treatment of chronic spontaneous urticaria in patients who remain symptomatic despite the use of H1 antihistamine and who are naïve to omalizumab	2021	Other	Trial registry w/out available results
Euctr, E. S	A Study of MTPS9579A in Participants with Refractory Chronic Spontaneous Urticaria	2021	Other	Trial registry w/out available results
Euctr, G. B	A clinical study to assess the efficacy and safety of Lanadelumab to prevent episodes of severe swelling in adolescents and adults	2020	Other	Trial registry w/out available results
Euctr, G. R	Efficacy and Safety of Tezepelumab for the Treatment of Chronic Spontaneous Urticaria	2021	Other	Trial registry w/out available results
Euctr, H. U	An extension study of long-term efficacy, safety and tolerability of remibrutinib in chronic spontaneous urticaria patients who completed preceding studies with remibrutinib	2022	Other	Trial registry w/out available results
Euctr, H. U	A study to compare SYN008 and Xolair for the treatment of chronic urticaria not well controlled by antihistamines	2021	Other	Trial registry w/out available results
Euctr, H. U	Dupilumab for the treatment of chronic spontaneous urticaria in patients who remain symptomatic despite the use of H1 antihistamine and who are naïve to, intolerant of, or incomplete responders to omalizumab	2020	Other	Trial registry w/out available results
Euctr, L. T	BP11 Versus EU-Approved Xolair® in Patients With Chronic Spontaneous Urticaria	2022	Other	Trial registry w/out available results
Euctr, N. L	Acute treatment and prophylaxis for acquired angioedema	2021	Other	Trial registry w/out available results
Euctr, S. K	A Study to Find Out if TEV-45779 Helps to Treat Chronic Idiopathic Urticaria/Chronic Spontaneous Urticaria That is Not Helped by Antihistamines	2021	Other	Trial registry w/out available results

Fayaz, Syed H. et al.	Loratadine vs Rupatadine: Unearthing the Capital Choice in Chronic Idiopathic Urticaria (CIU) - A Randomized Controlled Trial	2021	2nd gen AH vs 2nd gen AH	2nd gen AH vs 2nd gen AH
Gastaminza, G. et al.	Efficacy and Safety of Omalizumab (Xolair) for Cholinergic Urticaria in Patients Unresponsive to a Double Dose of Antihistamines: a Randomized Mixed Double-Blind and Open-Label Placebo-Controlled Clinical Trial	2019	Other	Study already included in previous review
Gayathri, Elango et al.	Comparative study on the efficacy and safety of bepotastine besilate versus levocetirizine in chronic spontaneous urticaria: A randomised, open-label, parallel study	2023	Bepotastine; 2nd gen AH vs 2nd gen AH	Bepotastine; 2nd gen AH vs 2nd gen AH
Gayathri, Elango et al.	Comparative study on the efficacy and safety of bepotastine besilate versus levocetirizine in chronic spontaneous urticaria: A randomised, open-label, parallel study	2023	Other	Duplicate
Ghosh, D. et al.	Biologic Pathways Involved In Chronic Spontaneous Urticaria And Response To Benralizumab Treatment	2021	Wrong S	Conference abstract; no concurrent treatment groups (repeated measures design); no clinical outcomes
Gildeeva, G. N. et al.	The results of a clinical study in relation to a new antihistamine medication teoritis in the treatment of patients with chronic spontaneous urticaria	2020		Teoritin (Russia) vs Desloratadine, no measure of spread reported efficacy outcomes; AEs reported
Gimenez-Arnau, A. et al.	Long-term safety and tolerability of remibrutinib (LOU064) in Phase 2b study in chronic spontaneous urticaria patients	2023	Wrong O	Poster; report based on remibrutinib does-finding study NCT04109313; no numerical outcomes reported
Gimenez-Arnau, A. et al.	Long-term safety and tolerability of remibrutinib (LOU064) in Phase 2b study in chronic spontaneous urticaria patients	2023	Other	Duplicate
Gimenez-Arnau, A. et al.	Long-term safety and tolerability of remibrutinib (LOU064) in Phase 2b study in chronic spontaneous urticaria patients	2023	Other	Duplicate
Gimenez-Arnau, A. et al.	Long-term safety and tolerability of remibrutinib (LOU064) in Phase 2b study in chronic spontaneous urticaria patients	2023	Other	Duplicate
Gimenez-Arnau, A. et al.	A Specialized Therapeutic Approach to Chronic Urticaria Refractory to H1-Antihistamines Improves Disease Burden: The Spanish AWARE Experience	2022		Retrospective study; outcome aggregated across different treatment group
Gimenez-arnau, A. et al.	More patients treated with ligelizumab are angioedema-free compared with omalizumab: Results of a phase ii clinical trial	2020		Conference abstract; only changes from baseline in percent but no measure of spread reported; instrument for assessment not specified
Gimenez-Arnau, A. M. et al.	IgE and high-affinity IgE receptor in chronic inducible urticaria, pathogenic, and management relevance	2022	Wrong S	Evaluation of treatment response based on IgE receptor expression; no clinical outcomes
Gimenez-Arnau, A. M. et al.	Evaluating complete control of urticaria with ligelizumab: A composite score of symptoms and quality-of-life outcome	2021	Other	Conference abstract; no baseline characteristics reported; see if more details on

				omalizumab vs placebo are reported elsewhere (ligelizumab Phase 2b trial)
Gimenez-Arnau, A. M. et al.	Disease control correlates with improvement of dermatology quality of life in CSU patients with angioedema treated with ligelizumab	2020		Subgroup analysis of NCT02477332 for patients with angioedema
Gimenez-Arnau, Ana et al.	Ligelizumab improves sleep interference and disease burden in patients with chronic spontaneous urticaria	2022	Wrong O	Report based on ligelizumab 2b study (NCT02477332); Additional outcomes for Omalizumab vs placebo (Weekly Sleep Interference Scores, Weekly Activity Interference Score, Dermatology Life Quality Index scores, and Overall Work Impairment), reported as time series plot and absolute change from baseline
Gimeno, R. et al.	Remibrutinib inhibits hives effector cells stimulated by serum from chronic urticaria patients independently of FcepsilonR1 expression level and omalizumab clinical response	2023	Wrong C	Evaluation of CD63 expression based on remibrutinib treatment; no control; no clinical outcomes
Godse, K. V. et al.	Subcutaneous auto serum therapy in chronic spontaneous urticaria	2020	Other	Conference abstract; autologous serum vs placebo; no measure of spread reported (only mean UAS)
Godse, K. V. et al.	Subcutaneous auto serum therapy in chronic spontaneous urticaria	2020	Other	Duplicate
Gorczyza, M. et al.	H1-antihistamine inhibition of histamine- and codeine-induced wheals does not predict response in chronic cold urticaria	2019		Additional report of NCT01605487. Original publication Abajian (2016) already included in 2016 review.
Goswamy, V. et al.	A Phase IV, Randomized, Double-Blind, Placebo-Controlled Exploratory Study of Omalizumab for Treatment of Idiopathic Angioedema in Patients Who Remain Symptomatic Despite Current Therapy	2022		Conference abstract; outcome dichotomously reported in terms of improvement of different scores (log odds of improvement omalizumab vs. placebo)
Goswamy, V. et al.	A Phase IV, Randomized, Double-Blind, Placebo-Controlled Exploratory Study of Omalizumab for Treatment of Idiopathic Angioedema in Patients Who Remain Symptomatic Despite Current Therapy	2022	Other	Duplicate
Goswamy, Vinay P. et al.	Omalizumab for treatment of idiopathic angioedema	2022		Idiopathic angioedema subpopulation; evaluation of Omalizumab as add-on to H1-AH (pooled across AH); Only 10 patients; report to NCT02966314; follow up only at week 28 and 36 (24-week treatment period) but IPD available as time series plot (very convoluted)

Goswamy, Vinay P. et al.	Omalizumab for treatment of idiopathic angioedema	2022	Other	Duplicate
Greiner, A. et al.	Remibrutinib Improves Chronic Spontaneous Urticaria in Patients Irrespective of Previous Anti-IgE Treatment: Results From a Phase 2b Study	2023	Other	Conference abstract; report based on remibrutinib phase 2b study NCT03926611; no measure of spread reported (only mean UAS change from baseline)
Grekowitz, Eva et al.	Targeting Histamine Receptor 4 in Cholinergic Urticaria with Izuforant (LEO 152020): Results from a Phase 2a, Randomised, Double-Blind, Placebo-Controlled, Multicentre, Crossover trial	2024	Wrong I	Izuforant (LEO 152020)
Hawe, E. et al.	PCR260 Influence of Disease Activity and Angioedema on EQ-5D-5L Utility Scores in Chronic Spontaneous Urticaria	2023	Other	No intervention study
Hayama, K. et al.	REMIBRUTINIB IMPROVES CHRONIC SPONTANEOUS URTICARIA IN PATIENTS WITH LOW OR HIGH IGE	2022	Other	Poster; no measure of spread reported (only median UAS change from baseline)
Hide, M. et al.	Real-world safety and effectiveness of omalizumab in Japanese patients with chronic spontaneous urticaria: A post-marketing surveillance study	2023	Wrong C	No control group
Hsu, C. et al.	42939 Remibrutinib Treatment Improves Itch and Sleep in Chronic Spontaneous Urticaria Patients: phase 2b Study Results	2023	Other	Conference abstract; report based on remibrutinib phase 2b study NCT03926611; outcomes: weekly Itch Severity Score, weekly Sleep Interference Score; outcome reporting only in terms of range or CI
Hua, L. et al.	Effect of levocetirizine hydrochloride on chronic urticaria and serum levels of total IgE and inflammatory factors	2023	Other	2nd gen AH vs 2nd gen AH
Irct20110531006660 N	Probiotic in chronic urticaria	2020	Wrong I	Probiotics
Irct20200406046967 N	Effect of Colchicine in treatment of chronic urticaria	2020	Other	Trial registry w/out available results
Irct20210407050878 N	Effect of naltrexone in chronic urticaria	2021	Other	Trial registry w/out available results
Irct20211219053449 N	Comparison of the effects of Cetirizine and Desloratadine on the symptoms of chronic spontaneous urticarial	2022	Other	Trial registry w/out available results
Irct20220205053947 N	Tranexamic acid in chronic urticaria	2022	Other	Trial registry w/out available results
Ismail, R. et al.	A comparison of autologous serum, plasma, and whole blood for intradermal autoreactivity testing in patients with chronic spontaneous urticarial: A cross-sectional study	2022	Wrong I	No intervention (autoreactivity testing)
Jorg, L. et al.	Double-blind placebo-controlled trial of the effect of omalizumab on basophils in chronic urticaria patients	2018		Study included in 2021 review

Jprn jRC	A study to investigate the pharmacokinetics and safety of dupilumab in participants ≥ 2 years to < 12 years of age with uncontrolled chronic spontaneous urticaria (CSU) or chronic inducible cold urticaria (CICU)	2023	Other	Trial registry w/out available results
Jprn jRC	Study of Efficacy and Safety of Omalizumab in Refractory Chronic Spontaneous Urticaria Patients	2015	Other	Trial registry w/out available results
Jprn jRC	Dose-finding Study of QGE031 as add-on Therapy to Evaluate Efficacy and Safety in Patients With CSU	2015	Other	Trial registry w/out available results
Jprn jRC	A Double-blind, Parallel-group Phase III Study of TK-041 in Patients with Chronic Urticaria	2015	Other	Trial registry w/out available results
jRct	A phase 2a study of TAS5315 in patients with chronic spontaneous urticaria	2022	Other	Trial registry w/out available results
Jung, M. J. et al.	A randomized, vehicle controlled clinical trial of a synthetic trpm8 agonist (Cryosim-1) gel for itch	2021	Wrong I	Cryosim- 1 gel (TRPM8 agonist)
Jung, Min Je et al.	A randomized, vehicle-controlled clinical trial of a synthetic TRPM8 agonist (Cryosim-1) gel for itch	2021	Wrong I	Cryosim- 1 gel (TRPM8 agonist)
Kalugina, V. et al.	The long-term monitoring and analysis of outcomes of different approaches to the management of chronic spontaneous in adolescents	2021		conference abstract; evaluation of omalizumab as add-on to H1-AH (pooled across AH); no follow-up < 6 months
Kaneko, S. et al.	Current status of the satisfaction levels of adult patients receiving drugs for atopic dermatitis and chronic urticaria	2022	Wrong S	No random treatment allocation; primary outcome measure new self-administered questionnaire; outcome pooled across antihistamines, cyclosporine, oral steroid, topical steroid, topical tacrolimus, moisturizer, biologics
Khemani, U. N. et al.	Efficacy of injection histaglobulin in treatment of chronic urticaria	2021	Wrong S	No control group
King, W. et al.	Benefits of a histamine-reducing diet for some patients with chronic urticaria and angioedema	2000	Wrong O	Only outcome reduction in AH-use reported numerically
Kiruba, D. et al.	Evaluate the efficacy of autologous serum therapy (AST) in patients with chronic idiopathic urticaria	2019	Other	Inaccessible (study not available on journal site)
Kolcu, M. et al.	The Use of Shotblocker for Subcutaneous Injection Pain, Anxiety and Satisfaction in Chronic Spontaneous Urticaria Patients: a Randomized Controlled Trial	2021	Wrong I	Shotblocker for injection pain
Kolkhir, P. et al.	Why is it important to use patient-reported outcome measures when treating CSU patients? Answers from the Chronic Urticaria Registry (CURE)	2023	Wrong S	Conference abstract; no intervention study (comparison of PROMs vs physician global assessment)
Kolkhir, P. et al.	The Benefit of Complete Response to Treatment in Patients With Chronic Spontaneous Urticaria-CURE Results	2023	Wrong S	No random treatment allocation; outcome reported in terms of dummy coded least-squares estimate (4 doses AH,

				omalizumab, systemic steroids, other treatment)
Konstantinou, George N. et al.	Omalizumab prevents respiratory illnesses in non-atopic chronic spontaneous urticaria patients: A prospective, parallel-group, pilot pragmatic trial	2023	Wrong O	Evaluation of cold symptoms
Korczynska-Krawczyk, Paulina et al.	The effect of levocetirizine and montelukast on clinical symptoms, serum level and skin expression of COX-1 and COX-2 enzymes in patients suffering from chronic autoimmune urticaria - a pilot study	2020		Autoimmune urticaria subpopulation; Outcome only reported in terms of UAS improvement (yes/no)
Kubaisi, T. A	Regular sports exercises as a supportive therapeutic choice in cholinergic urticaria	2023	Wrong I	Sports exercises
Kulumbegov, B. et al.	Interleukin-33, endothelin-1, and inflammatory parameters in chronic spontaneous urticaria	2023	Wrong S	No full text available; comparison of different markers of treatment sensitivity; no treatment specified
Kumar, S. et al.	Comparative evaluation of the therapeutic efficacy and safety of injected histaglobulin versus autologous serum therapy in chronic urticaria	2021	Wrong I	IVIG vs autologous serum therapy; only w1 to final analysis mean, not CFB reported; no dichotomous outcomes
Le, M. et al.	Ligelizumab: Anti-IgE monoclonal antibody, Treatment of urticaria	2021	Other	Review article
Leducq, S. et al.	Evaluation of a low-dose methotrexate added to H1-antihistamines regimen for severe chronic spontaneous urticaria: a phase iii, randomized, placebocontrolled trial	2020	Wrong O	MTX + AH vs AH; only outcome for week 18 reported; full text inaccessible
Li, X. et al.	COMBINATION OF DIFFERENT ANTIHISTAMINES TO TREAT URTICARIA AND ITS EFFECTS ON SERUM TOTAL IMMUNOGLOBULIN E LEVEL IN PATIENTS	2023		2nd gen vs 2nd + 1st gen: desloratadine vs desloratadine + chlorphenamine + ranitidine + vitamin c -> exclude (chlorphenamine not explicitly mentioned)
Li, Y. et al.	Acrivastine combined with loratadine in the treatment of chronic refractory urticaria: a multicenter, randomized controlled study	2020		Acrivastine + loratadine vs acrivastine + placebo; full text inaccessible
Lin, W	The effect and safety of desloratadine citrate disodium in the therapy of chronic urticaria	2020	Other	Conference abstract; desloratadine vs levocetirizine; outcome only reported in terms of statistical significance
Maul, Julia-Tatjana et al.	Canakinumab Lacks Efficacy in Treating Adult Patients with Moderate to Severe Chronic Spontaneous Urticaria in a Phase II Randomized Double-Blind Placebo-Controlled Single-Center Study	2021		Canakinumab
Maurer, M. et al.	Safety and Clinical Activity of Multiple Doses of Barzolvolimab, an anti-KIT Antibody, in Patients with Chronic Spontaneous Urticaria	2023	Wrong C	Barzolvolimab; only different doses of single drug compared against each other
Maurer, M. et al.	Remibrutinib (LOU064) reduces the use of rescue medication in patients with	2023		Analysis of rescue medication use, original trials:

	chronic spontaneous urticaria: Findings from a Phase 2b study			NCT03926611, NCT04109313 (extension study) -> no outcome of interest
Maurer, M. et al.	Remibrutinib (LOU064) reduces the use of rescue medication in patients with chronic spontaneous urticaria: Findings from a Phase 2b study	2023	Other	Duplicate
Maurer, M. et al.	Ligelizumab is effective in chronic spontaneous urticaria patients with and without serum autoreactivity assessed by basophil histamine release assay	2023		Already considered via NCT02477332; supplementary analysis for BHRA- vs. BHRA+ at BL relevant for SR?
Maurer, M. et al.	Ligelizumab is effective in chronic spontaneous urticaria patients with and without serum autoreactivity assessed by basophil histamine release assay	2023	Other	Duplicate
Maurer, M. et al.	Dupilumab significantly reduces itch in patients with chronic spontaneous urticaria: results from a Phase 3 Trial (LIBERTY-CSU CUPID study A)	2023	Other	Conference abstract reporting on NCT04180488, no outcomes not already reported in main publication at https://www.sciencedirect.com/science/article/pii/S0091674924001969?via%3Dihub
Maurer, M. et al.	Dupilumab efficacy in patients with chronic spontaneous urticaria by IgE level: LIBERTYCSU CUPID Study A	2023	Other	Conference abstract reporting on NCT04180488, no outcomes not already reported in main publication at https://www.sciencedirect.com/science/article/pii/S0091674924001969?via%3Dihub
Maurer, M. et al.	Dupilumab Improves Urticaria Activity And Quality Of Life In Patients With Chronic Spontaneous Urticaria (CSU)	2023		Conference abstract reporting on NCT04180488, contains quality of life information not reported in main publication at https://www.sciencedirect.com/science/article/pii/S0091674924001969?via%3Dihub ; outcome reporting for study >12 weeks (24w)
Maurer, M. et al.	42011 Dupilumab Improves Urticaria Signs and Symptoms and Quality of Life in Patients With Chronic Spontaneous Urticaria (CSU)	2023		Conference abstract reporting on NCT04180488, contains quality of life information not reported in main publication at https://www.sciencedirect.com/science/article/pii/S0091674924001969?via%3Dihub ; check for additional data to above report; outcome reporting for study >12 weeks (24w)
Maurer, M. et al.	Dupilumab Significantly Reduces Itch and Hives in Patients With Chronic Spontaneous Urticaria: results From a Phase 3 Trial (LIBERTY-CSU CUPID Study A)	2022	Other	Duplicate
Maurer, M. et al.	DUPILUMAB EFFICACY IN PATIENTS WITH CHRONIC SPONTANEOUS URTICARIA BY IGE LEVEL: LIBERTY-CSU CUPID STUDY A	2022	Other	Duplicate

Maurer, M. et al.	33004 Dupilumab significantly reduces itch and hives in patients with chronic spontaneous urticaria (CSU) who remain symptomatic despite use of standard-of-care antihistamines: Results from a phase 3 trial (LIBERTY-CSU CUPID study A)	2022	Other	Duplicate
Maurer, M. et al.	Treatment with ligelizumab achieves over forty percent higher complete response rate in CSU patients originally treated with omalizumab	2021	Other	Already considered via NCT02477332
Maurer, M. et al.	Retreatment with ligelizumab achieves over forty percent higher complete response rate in patients with chronic spontaneous urticaria originally treated with omalizumab	2021	Other	Already considered via NCT02477332
Maurer, M. et al.	Ligelizumab as add-on therapy for patients with anti-H1- refractory CSU: Primary results of a placebo- and activecontrolled phase 2b dose-finding study	2021	Other	Already considered via NCT02477332
Maurer, M. et al.	Ligelizumab achieves fast control of symptoms in patients with chronic spontaneous urticaria: A rolling UAS7 analysis	2021	Other	Already considered via NCT02477332
Maurer, M. et al.	Treatment with ligelizumab achieves over forty percent higher complete response rate in chronic spontaneous urticaria patients originally treated with omalizumab	2020	Other	Already considered via NCT02477332
Maurer, M. et al.	Effect of omalizumab treatment on disease activity in chronic spontaneous/idiopathic urticaria: Results from xtend-ciu, a longitudinal perspective	2020	Other	Conference abstract reporting on results of XTEND-CIU study NCT02392624; original study already included in previous SR
Maurer, Marcus et al.	Efficacy and safety of ligelizumab in adults and adolescents with chronic spontaneous urticaria: results of two phase 3 randomised controlled trials	2024	Other	Duplicate
Maurer, Marcus et al.	Efficacy and safety of ligelizumab in adults and adolescents with chronic spontaneous urticaria: results of two phase 3 randomised controlled trials	2024	Other	Duplicate
Maurer, Marcus et al.	Sustained safety and efficacy of ligelizumab in patients with chronic spontaneous urticaria: A one-year extension study	2022		Conference abstract reporting on NCT02649218, Ligelizumab extension study
Metz, M. et al.	Angioedema control with ligelizumab in patients with chronic spontaneous urticaria correlates with improvement of health-related quality-of- life	2023	Other	Conference abstract reporting on NCT02477332 and NCT02649218; pooled analysis across different treatments to establish association between angioedema activity score and DLQI
Metz, M. et al.	Fenebrutinib in refractory chronic spontaneous urticaria	2020		Conference abstract reporting on EudraCT ID 2016-004624-35; unclear whether Fenebrutinib should be included

Maurer, M. et al.	Remibrutinib Treatment Improves Quality of Life in Patients with Chronic Spontaneous Urticaria	2022		Conference abstract reporting on NCT03926611, all information already contained in main report
Metz, Martin et al.	Ligelizumab improves angioedema, disease severity and quality-of-life in patients with chronic spontaneous urticaria	2022	Other	Duplicate
Metz, Martin et al.	Fenebrutinib in H1 antihistamine-refractory chronic spontaneous urticaria: a randomized phase 2 trial	2021		Main report for EudraCT ID 2016-004624-35; unclear whether Fenebrutinib should be included
Mohamed, A. A. et al.	Efficacy and safety of active vitamin D supplementation in chronic spontaneous urticaria patients	2022	Wrong I	Vitamin D
Monteseirini, J. et al.	Cinnarizine: a double-blind study in patients with chronic urticaria	1992	Wrong I	Cinnarizine; Study from 1992
Mosnaim, G. et al.	PATIENTS WITH CHRONIC SPONTANEOUS URTICARIA MAY BENEFIT FROM LONGER TREATMENT OR UPDOSING WITH OMALIZUMAB	2022	Wrong S	Post-hoc subgroup analysis of NCT02392624, XTEND-CIU
Metz, Martin et al.	Ligelizumab improves angioedema, disease severity and quality-of-life in patients with chronic spontaneous urticaria	2022		Full text for DLQI-analysis of NCT02477332 and NCT02649218; pooled analysis across different treatments; no treatment-specific DLQI data for relevant follow-up time
Nabavizadeh, Seyed Hesamedin et al.	The effect of vitamin D add-on therapy on the improvement of quality of life and clinical symptoms of patients with chronic spontaneous urticaria	2023	Wrong I	Vitamin D
Namazova-Baranova, L. et al.	The results of long-term observation of adolescents with chronic spontaneous urticaria	2020	Wrong O	Long-term observation of omalizumab as add-on vs. H1-AHs; earliest follow-up reported at 6 months
Naseemullah, et al.	Efficacy of Intramuscular Platelet Rich Plasma Versus Oral Antihistamine In Chronic Urticaria	2022		PRP alone vs AH alone; Type of antihistamine [1st or 2nd gen] and treatment regimen not specified
Natarajan, S. et al.	Open-label non-blinded cohort study on anti-histaminic resistant chronic idiopathic urticaria in Western India	2022	Other	Cyclosporine vs. AH; between-group comparison in UTSS and UAS7 only reported as p-values and time series plot without any measure of spread, Aes only reported for whole observation timeframe
Nct	Study to Compare Efficacy Safety and Immunogenicity of ADL-018 With XOLAIR (Omalizumab) in Adults With Chronic Idiopathic Urticaria	2023	Other	Trial registry w/out available results
Nct	Study to Assess the Safety, Tolerability, Pharmacokinetics and Immunogenicity of AK006 in Healthy Subjects and Subjects With Chronic Spontaneous Urticaria	2023	Other	Trial registry w/out available results

Nct	Study Evaluating the Efficacy and Safety of Povorcitinib in Adults With Chronic Spontaneous Urticaria	2023	Other	Trial registry w/out available results
Nct	Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Effects of EP262 in Subjects With Chronic Spontaneous Urticaria	2023	Other	Trial registry w/out available results
Nct	Extending Omalizumab Treatment Intervals in Patients With Chronic Spontaneous Urticaria	2023	Other	Trial registry w/out available results
Nct	Dose Escalation Trial Of Safety, Pharmacokinetic/Pharmacodynamic And Preliminary Clinical Activity of Briquilimab In Adult Patients With Chronic Spontaneous Urticaria (CSU)	2023	Other	Trial registry w/out available results
Nct	A Study to Investigate Efficacy, Safety, and Tolerability of Remibrutinib Compared With Placebo in Adults With CINDU Inadequately Controlled by H1-antihistamines	2023	Other	Trial registry w/out available results
Nct	A Phase 3b Study to Assess the Efficacy, Safety, and Tolerability of Remibrutinib in Comparison to Placebo and With Omalizumab as Active Control in CSU Adult Patients	2023	Other	Trial registry w/out available results
Nct	Safety and Efficacy of TLL018 in Patients With Chronic Spontaneous Urticaria	2022	Other	Trial registry w/out available results
Nct	Safety and Efficacy of Intranasal Epinephrine After Administration of ARS -1 in Subjects With Frequent Urticaria Flares	2022	Other	Trial registry w/out available results
Nct	A Study to Evaluate the Pharmacodynamics, Pharmacokinetics, Safety, and Efficacy of UB-221 IV Infusion as an add-on Therapy in Patients With Chronic Spontaneous Urticaria	2022	Other	Trial registry w/out available results
Nct	A Study to Assess Subcutaneous Lirentelimab (AK002) in Chronic Spontaneous Urticaria	2022	Other	Trial registry w/out available results
Nct	24 Weeks Double-blind Randomized Placebo-controlled Trial to Evaluate Efficacy, PK, Safety of LOU064 in Adolescents (12 - <18) With CSU and Inadequate Response to H1-antihistamine Followed by Optional 3 Years Open-label Extension and an Optional 3 Years Safety Long-term Treatment-free Follow-up	2022	Other	Trial registry w/out available results; estimated completion 2025-10-30
Nct	Using Doxepin for Urticaria	2021	Other	Trial registry w/out available results
Nct	Study to Evaluate the Therapeutic Equivalence of SYN008 Versus Xolair® in the Treatment of Patients With Refractory Chronic Spontaneous Urticaria	2021	Other	Trial registry w/out available results

Nct	Study to Evaluate the Efficacy, Safety, and Tolerability of Tirabrutinib in Participants With Antihistamine-Resistant Chronic Spontaneous Urticaria	2021	Other	Trial registry; study withdrawn
Nct	Study to Compare Efficacy and Safety of TEV-45779 With XOLAIR (Omalizumab) in Adults With Chronic Idiopathic Urticaria	2021	Other	Trial registry w/out available results
Nct	Rilzabrutinib for the Treatment of Chronic Spontaneous Urticaria in Patients Who Remain Symptomatic Despite the Use of H1 Antihistamine	2021	Other	Trial registry w/out available results
Nct	Efficacy of Low-dose Interleukin-2 Treatment in Chronic Spontaneous Urticaria	2021	Other	Trial registry w/out available results
Nct	A Phase 3 Study of Efficacy and Safety of Remibrutinib in the Treatment of CSU in Adults Inadequately Controlled by H1 Antihistamines	2021	Other	Trial registry w/out available results
Nct	A Phase 3 Study of Efficacy and Safety of Remibrutinib in the Treatment of CSU in Adults Inadequately Controlled by H1 Antihistamines	2021	Other	Duplicate
Nct	Treatment of Angiotensin Converting Enzyme Inhibitor-induced Angioedema	2020	Other	Trial registry; results posted but indicate discontinuation (only two participants); treatment = High ACE Activity Fresh Frozen Plasma
Nct	To Compare Efficacy and Safety of CT-P39 and EU-approved Xolair in Patients With Chronic Spontaneous Urticaria	2020	Other	Trial registry w/out available results
Nct	Study of Pharmacokinetics, Pharmacodynamics and Safety Assessment of GNR-044 (JSC GENERIUM, Russia) and Xolair®	2020	Other	Trial registry w/out available results; completion in 2017
Nct	Study of Mechanism of Action of Ligelizumab (QGE031) in Patients With Chronic Urticaria	2020	Other	Trial registry w/out available results; study terminated
Nct	Study to Evaluate Tezepelumab in Adults With Chronic Spontaneous Urticaria	2021		Trial registry; outcome assessment only available for weeks 16 and 32 -> revisit to retrieve publication rather than trial registry entry
Nct	A Study to Evaluate Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of UCB8600 in Healthy Participants, Atopic Participants, and Chronic Spontaneous Urticaria Participants	2020	Other	Trial registry w/out available results; study terminated
NI	Oral PHA-022121 for the acute treatment and prophylaxis Of angioedema attacks in Patients with Acquired C1-Inhibitor Deficiency	2021	Other	Trial registry w/out available results; study terminated
Ozciftci Ertugral, N. et al.	The causes and treatment responses of angioedema in pediatric patients	2023	Other	Only number of patients with treatment response to AHs reported but not specified in what that consists nor which AHs had been taken

Ozen, B. et al.	An evaluation of the factors affecting the clinical and laboratory findings, prognosis, and treatment response in children with chronic urticaria	2022		Retrospective study; H1 and H2-AHs in different doses, montelukast and omalizumab prescribed contingent on urticaria control; data likely insufficient for MA
Pesque, D. et al.	Autoimmune Diseases and Low Baseline IgE in Chronic Spontaneous Urticaria: A Clinical and Therapeutic Prospective Analysis in Real-Life Clinical Practice	2023		Observational study; AHs, omalizumab and cyclosporine use assessed at six months only; data likely insufficient for MA (only p-values based on multiple regression)
Plavsic, A. et al.	C-reactive protein in chronic spontaneous urticaria: Correlation with disease activity, duration and therapy	2020	Wrong S	Conference abstract; no information on nature of treatment received and treatment-specific clinical outcome
Podder, Indrashis et al.	Effectiveness, safety, and tolerability of bilastine 20 mg vs levocetirizine 5 mg for the treatment of chronic spontaneous urticaria: A double-blind, parallel group, randomized controlled trial	2020	Other	Duplicate
Podder, Indrashis et al.	Effectiveness, safety, and tolerability of bilastine 20 mg vs levocetirizine 5 mg for the treatment of chronic spontaneous urticaria: A double-blind, parallel group, randomized controlled trial	2020		2nd generation vs 2nd generation
Rai, A. K. et al.	A double-arm, randomized, and controlled trial to compare the efficacy and safety of bepotastine with levocetirizine in patients of chronic spontaneous urticaria	2022	Wrong I	Bepotastine vs. levocetirizine
Prosty, C. et al.	Cold urticaria in a pediatric cohort: Clinical characteristics, management, and natural history	2022		Only annual follow-up data available; Ahs pooled and compared against cold-avoidance (n=3) and omalizumab (n=1)
Raja, T. et al.	A randomized single blinded study comparing efficacy of bilastine versus cetirizine in autoimmune urticaria	2020	Other	Duplicate
Rodriguez, M. et al.	Pharmacokinetics and safety of bilastine in children aged 6 to 11 years with allergic rhinoconjunctivitis or chronic urticaria	2020	Wrong S	Bilastine vs. cetirizine; only pharmacokinetic outcomes reported; comparison relevant (two 2nd generation AHs)?
Raja, T. et al.	A randomized single blinded study comparing efficacy of bilastine versus cetirizine in autoimmune urticaria	2020		Conference abstract; bilastine vs. cetirizine; comparison relevant (two 2nd generation AHs)?
Saini, S. S. et al.	Efficacy and Safety of Omalizumab in Patients with Chronic Idiopathic/Spontaneous Urticaria who Remain Symptomatic on H1 Antihistamines: a Randomized, Placebo-Controlled Study	2015	Other	Corrigendum to https://doi.org/10.1038/jid.2014.306 ; original study (ASTERIA) included in 2021 SR
Sanchez-Diaz, M. et al.	Risk Factors of Quality-Of-Life and Sexual Function Impairment in Chronic	2023	Wrong S	Cross-sectional study on Quality-Of-Life and Sexual Function Impairment;

	Spontaneous Urticaria Patients: Cross-Sectional Study			treatment recorded but outcome not reported for individual treatment groups
Sekerel, B. E. et al.	Study design and rationale of a phase 2b dose-finding study of ligelizumab in adolescent patients with chronic spontaneous urticaria	2021		Conference poster; protocol for dose-finding extension study to NCT02477332; no outcome data
Severin, T. et al.	Study design and rationale of a phase 3b extension study of ligelizumab in adult and adolescent patients with chronic spontaneous urticaria	2020		Conference poster; protocol for dose-finding extension study to PEARL 1 & 2; no outcome data
Shulzhenko, A. E. et al.	Comparative analysis of clinical efficacy and safety of omalizumab biosimilar in the treatment of patients with chronic spontaneous urticaria	2023	Wrong C	Russian omalizumab product (Genolair) vs. Xolair; article in Russian
Siddiqua, S. A. et al.	The Efficiency and Safety of Olopatadine against Rupatadine in Chronic Urticaria of Idiopathic Origin: a Comparative Study	2020	Wrong I	Olopatadine vs. rupatadine
Sil, A. et al.	An investigator-blind randomised controlled trial comparing the effectiveness, safety and tolerability of levocetirizine and bepotastine in chronic urticaria	2020	Other	Duplicate
Sil, A. et al.	An investigator-blind randomised controlled trial comparing the effectiveness, safety and tolerability of levocetirizine and bepotastine in chronic urticaria	2020	Other	Duplicate
Sil, Amrita et al.	An Investigator-Blind Randomized Controlled Trial Comparing Effectiveness, Safety of Levocetirizine and Bepotastine in Chronic Urticaria	2021	Wrong I	Bepotastine vs. levocetirizine
Shah, Bela et al.	A Comparative, Three-Arm, Randomized Clinical Trial to Evaluate the Effectiveness and Tolerability of Bilastine vs Fexofenadine vs Levocetirizine at the Standard Dose and Bilastine vs Fexofenadine at Higher Than the Standard Dose (Up-Dosing) vs Levocetirizine and Hydroxyzine (in Combination) in Patients with Chronic Spontaneous Urticaria	2022		Bilastine vs. Fexofenadine vs. Levocetirizine; comparison relevant (three 2nd generation AHs)?
Sitz, K. et al.	Ligelizumab Achieves Freedom from Signs and Symptoms of Chronic Spontaneous Urticaria Regardless of the CU Index (Basophil Histamine Release Assay) Status at Baseline	2022	Wrong I	Conference abstract; post-hoc subgroup analysis of NCT03437278 (Ligelizumab phase 2b trial) contingent on BHRA-status; only outcomes for ligelizumab vs. omalizumab reported
Sitz, K. et al.	33583 Patients treated with ligelizumab achieve freedom from signs and symptoms of chronic spontaneous urticaria regardless of the angioedema status at baseline	2022	Wrong I	Conference abstract; post-hoc subgroup analysis of NCT03437278 (Ligelizumab phase 2b trial) contingent on angioedema-status; only outcomes for ligelizumab vs. omalizumab reported

Sitz, K. et al.	Ligelizumab is more effective in patients with chronic spontaneous urticaria previously treated with omalizumab	2021	Wrong I	Conference abstract; post-hoc subgroup analysis of NCT03437278 (Ligelizumab phase 2b trial) contingent on prior omalizumab treatment; only outcomes for ligelizumab vs. omalizumab reported
Soong, W. et al.	Ligelizumab Improves Dermatology Quality Of Life In Patients With Chronic Spontaneous Urticaria Regardless of Angioedema Status At Baseline	2022	Wrong I	Conference abstract; post-hoc subgroup analysis of NCT03437278 (Ligelizumab phase 2b trial) contingent on angioedema-status; outcomes for ligelizumab vs. omalizumab vs. placebo reported
Soong, W. et al.	Prolonged symptom control with long-term ligelizumab treatment in patients with chronic spontaneous urticaria during post-treatment follow-up	2021	Wrong O	Conference abstract reporting on NCT02477332 and NCT02649218 (Ligelizumab 2b + extension study); time series analysis via Kaplan-Mayer mentioned but only cross-sectional data reported (Week 20 and 52)
Soong, W. et al.	Prolonged symptom control with long-term ligelizumab treatment in patients with chronic spontaneous urticaria during post-treatment follow-up	2021	Other	Duplicate
Soong, W. et al.	Long-term ligelizumab treatment leads to prolonged symptom control during post-treatment follow-up in patients with chronic spontaneous urticaria	2021	Wrong O	Conference abstract reporting on NCT02477332 and NCT02649218 (Ligelizumab 2b + extension study); only outcomes for ligelizumab vs. omalizumab reported at weeks 20 and 52
Soong, W. et al.	LIGELIZUMAB ACHIEVES FREEDOM FROM DISEASE ACTIVITY IN CHRONIC SPONTANEOUS URTICARIA REGARDLESS OF PREVIOUS H1-ANTIHISTAMINE DOSE	2021	Wrong I	Conference abstract; post-hoc subgroup analysis of NCT03437278 (Ligelizumab phase 2b trial) contingent on prior AH1-treatment; only outcomes for ligelizumab vs. omalizumab reported
Soong, W. et al.	Long-term treatment with ligelizumab achieves prolonged symptom control in patients with chronic spontaneous urticaria during the post-treatment follow-up	2020	Other	Duplicate
Sussman, G. et al.	Omalizumab Re-Treatment and Step-Up in Patients with Chronic Spontaneous Urticaria: OPTIMA Trial	2020	Other	Conference abstract reporting on NCT02161562 (Omalizumab step-up trial OPTIMA); original study excluded in 2021 SR
Sinha, Vishakha V. et al.	Comparative study of efficacy and safety of cetirizine and bilastine in patients of chronic spontaneous urticaria: Open-label, randomized, parallel-group study	2023		Bilastine vs cetirizine; comparison relevant (two 2nd generation AHs)?
Tagka, A. et al.	Time-dependent effects in chronic urticaria: A time-series perspective of omalizumab treatment	2020	Other	Article inaccessible; likely reporting on same cohort as Tagka, 2021

Talukdar, K	A randomized, double-blind, placebocontrolled study of monoclonal antiige antibody omalizumab in the management of pruritus in chronic spontaneous urticaria in the pediatric population	2020	Other	Conference abstract; omalizumab vs. placebo in children; no numerical outcomes reported
Tctr	Butyrate supplements improve efficacy in patients with moderate to severe chronic spontaneous urticaria, A randomized, double-blind, placebo-controlled trial	2022	Other	Trial registry w/out available results
Williams, M. et al.	Remibrutinib: A Novel BTKi in Development for MS With a Favorable Safety Profile in Various Autoimmune Disorders	2023	Other	Conference abstract reporting on Remibrutinib phase 2b trial; no numerical outcomes reported
Wu, K. C. et al.	Omalizumab, an Anti-IgE mAb, receives approval for the treatment of chronic idiopathic/spontaneous urticaria	2015	Wrong S	Review article on extant trials on omalizumab
Xiao, C. C. et al.	Clinical observation of setastine combined with tripterygium glycosides tablet for the treatment of chronic urticaria	2019	Wrong I	Setastine vs. setastine with tripterygium glycosides
Tagka, A. et al.	Omalizumab in the treatment of chronic urticaria: The effect of drug co-administration and co-morbidities	2021		Omalizumab alone vs omalizumab + various medications (AH, cyclosporine, AH + corticosteroids); protocol-based treatment confounded by necessity (choice of treatment contingent on severity/lack of response)
Ye, Y. et al.	A randomized open labeled trial to compare the efficacy of antihistamine dosing-up and add-on treatment with H2-receptor antagonist in patients with chronic urticaria	2020	Other	Conference poster to Kim, 2023 (full report); different H1AH-regimes + change to / add-on treatment with H2RA
Zheng, Y. et al.	Population PK-PD and exposure-response modeling and simulation to support dose recommendation of xolair in chronic idiopathic urticaria/chronic spontaneous urticaria	2014	Wrong S	Conference abstract; pharmacokinetic-pharmacodynamic modeling study

Notes on reasons for exclusion: P = Population; I = Intervention; C = Comparison; O = Outcome; S = study type

ABBREVIATIONS

AEs	Adverse events
AH	Antihistamines
BID	Twice a day
CI	Confidence interval
CIndU	Chronic inducible urticaria
CU/CSU	Chronic urticaria, chronic spontaneous urticaria
GRADE	Grading of Recommendations Assessment, Development and Evaluation
EtD	Evidence-to-Decision frameworks
ITT	Intention-to-treat
MD	Mean difference
PICO	Patient - Intervention - Comparison - Outcome
PP	Per-protocol
QD	Once a day
QW	Once a week
RCT	Randomized controlled trials
RR	Risk ratio
SD	Standard deviation
SoF	Summary of findings