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Thyroid outcomes and response to Omalizumab for chronic spontaneous urticaria patients: A systematic review and meta-analysis

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Corresponding author:
Pintip Ngamjanyaporn

pintip.nga@mahidol.ac.th

Author Affiliation:
Division of Allergy, Immunology and Rheumatology, Department of Medicine, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Thailand.

Untaaveesup, S; Sutithavinkul, T; Leelakanok, N; Maneenawa, N; Piriyasanguanpong, W; Homob, W; Jaengthong, P; Jitpakdee, P; Prasartsak, A; Kantagowit, P; Supsrisunjai, C; Ngamjanyaporn, P.

ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Piloting of the study selection process.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2025100070

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 October 2025 and was last updated on 19 October 2025.

INTRODUCTION

Review question / Objective Chronic spontaneous urticaria is defined as wheal or flare for more than 6 weeks, after excluding other causes. Patients with refractory antihistamine treatment receive omalizumab. However, the effect of thyroid disease on omalizumab responsiveness is unclear.
Consequently, this meta-analysis aims to elucidate thyroid disease factors of omalizumab responsiveness in chronic spontaneous urticaria.

Condition being studied Chronic spontaneous urticaria, omalizumab.

METHODS

Search strategy We will use three databases, including MEDLINE, EMBASE, and Central databases, from inception up to October 2024.

Participant or population Patients with chronic spontaneous urticaria.

Intervention Patients who received omalizumab.

Comparator Patients who received placebo, any treatment or intervention.

Study designs to be included We will include randomized and non-randomized controlled studies, that reported the predictor factors of thyroid disease on omalizumab responsiveness.

Eligibility criteria We will include English publications that reported the predictive factors of thyroid illness and omalizumab responsiveness in patients with chronic spontaneous urticaria. Types of studies are randomized and non-randomized studies. We will exclude case reports, case series, and review articles.

Information sources MEDLINE, EMBASE, and Central databases.

Main outcome(s) The predictors of thyroid disease responsive to omalizumab from any assessment instrument, such as Weekly Urticaria Activity Score (UAS7) in individuals with chronic spontaneous urticaria.

Additional outcome(s) None.

Data management Nine researchers will conduct two rounds of screening through Covidence. Any disagreement will be resolved through discussion. The eligible articles will be extracted from the following data, including Authors, year of publication, type of study, baseline characteristics of participants, such as sex, mean age, mean BMI, baseline lab parameters, and number of participants. Any disagreement during the process will be discussed.

Quality assessment / Risk of bias analysis We will independently assess the quality of articles, including the Cochrane risk-of-bias tool for randomized trials (RoB 2) for the randomized controlled trial and the Newcastle-Ottawa Scale (NOS) tool for observational studies.

Strategy of data synthesis We will pool the interested outcomes, encompassing odds ratios with their 95% confidence interval and means with standard deviation by the generic inverse variance method of DerSimonian and Laird with a random effect model. The heterogeneity will be assessed by I^2.

Subgroup analysis None.

Sensitivity analysis None.

Language restriction English.

Country(ies) involved Thailand.

Other relevant information None.

Keywords Meta-analysis; Omalizumab; urticaria.

Contributions of each author

Author 1 - Suvijak Untaaveesup - conceptualization, methodology, interpretation, validation, resources, data curation, formal analysis, investigation, visualization, project administration, writing-original draft.
Email: suvijak2541@gmail.com
Author 2 - Tanpichcha Sutithavinkul - conceptualization, methodology, interpretation, validation, investigation, resources, data curation, writing-original draft.
Author 3 - Nattawut Leelakanok - conceptualization, methodology, interpretation, validation, project administration, visualization, formal analysis, investigation, supervision, project administration, writing-review & editing.
Author 4 - Nichata Maneenawa - conceptualization, methodology, interpretation, validation, investigation, resources, data curation.
Author 5 - Warot Piriyasanguanpong - conceptualization, methodology, interpretation, validation, investigation, resources, data curation.
Author 6 - Woramon Homob - conceptualization, methodology, interpretation, validation, investigation, resources, data curation.
Author 7 - Pornchita Jaengthong.
Author 8 - Polpatt Jitpakdee - conceptualization, methodology, interpretation, validation, investigation, resources, data curation.
Author 9 - Anunchuda Prasartsak -conceptualization, methodology, interpretation, validation, investigation, resources, data curation .
Author 10 - Piyawat Kantagowit - conceptualization, methodology, interpretation, validation, investigation, resources, data curation.
Author 11 - Chavalit Supsrisunjai - conceptualization, methodology, interpretation, validation, project administration, visualization, supervision, project administration, writing-review & editing.
Author 12 - Pintip Ngamjanyaporn - conceptualization, methodology, interpretation, validation, project administration, visualization, supervision, project administration, writing-review & editing.