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Related factors of D-dimer levels in response to Omalizumab for chronic spontaneous urticaria: A systematic review and meta-analysis

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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: INPLASY202640081

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 April 2026 and was last updated on 24 April 2026.

INTRODUCTION

Review question / Objective This systematic review and meta-analysis aims to review and evaluate D-dimer levels in response to omalizumab in chronic spontaneous urticaria (CSU).

Rationale Omalizumab is an anti-IgE treatment utilized for unresponsiveness to updosing antihistamines in patients with CSU. However, evidence for baseline D-dimer levels related to omalizumab responsiveness remained inconclusive. Hence, this meta-analysis aims to review and assess D-dimer levels in response to omalizumab in CSU.

Condition being studied Urticaria; chronic urticaria; D-dimer; fibrin fragment D; meta-analysis.

METHODS

Search strategy Three databases, comprised of MEDLINE, EMBASE, and Central databases, will be employed for evaluation. We will use pertinent keywords, such as chronic spontaneous urticaria, omalizumab, and D-dimer, for published articles from initiation until October 2024.

Participant or population CSU patients who were administered omalizumab injection.

Intervention Patients who had a response or an early response to omalizumab administration.

Comparator Patients who had no response or a delayed response to omalizumab administration.

Study designs to be included We will review published observational studies and randomized controlled trials for outcome assessment.

Eligibility criteria Published studies that detailed examining baseline D-dimer levels and response to omalizumab will be evaluated. Additionally, only English studies will be reviewed.

Information sources Three databases, including MEDLINE, EMBASE, and Central databases, will be recruited for comprehensive review.

Main outcome(s) The main outcome will be the association between baseline D-dimer levels and response outcome after omalizumab injection in patients with CSU. Moreover, disease activity will be assessed from any implements, including the Urticaria Activity Score (UAS) or Weekly Urticaria Activity Score (UAS7).

Additional outcome(s) None.

Data management Two rounds of article screening will be conducted through Covidence, an online platform for article screening. First, title and abstract evaluation will be manipulated independently, then researchers will evaluate the full text for eligible study recruitment. We will discuss any conflicts for the final decision.
The data from the included studies will be fulfilled in the data extraction form, such as first author, year of published study, number of participants, number of response treatments in each group, and tools for disease activity evaluation. Any dispute will be discussed for the final agreement.

Quality assessment / Risk of bias analysis The quality assessment will be conducted depending on study types. For the randomized controlled trial, we will employ the Cochrane risk-of-bias tool. The Newcastle-Ottawa Scale (NOS) tool will be used for observational studies assessment.

Strategy of data synthesis The generic inverse variance method of DerSimonian and Laird with a random effect model will be employed for pooled outcome computation. For dichotomous outcomes, we will pool odds ratios with their 95% confidence interval (95% CI). Additionally, means with standard deviation between groups will be calculated for pooled mean difference and standardized mean difference with their 95% CI. The heterogeneity in each analysis will be calculated by I2.

Subgroup analysis None.

Sensitivity analysis None.

Language restriction English.

Country(ies) involved Thailand.

Other relevant information None

Keywords urticaria; chronic urticaria; D-dimer; fibrin fragment D; meta-analysis.

Contributions of each author

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