

# Efficacy and safety of treatment with omalizumab for chronic spontaneous urticaria- a systematic review for the EAACI Biologicals Guidelines

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## Abstract

This systematic review evaluates the efficacy and safety of omalizumab for chronic spontaneous urticaria (CSU). Pubmed,

EMBASE and Cochrane Library were searched for RCTs. Critical and important CSU-related outcomes were considered. The risk of bias and the certainty of the evidence were assessed using GRADE. Ten RCTs including 1620 subjects aged 12 to 75 years old treated with omalizumab for 16 to 40 weeks were evaluated. Omalizumab 150 mg: does not result in clinically meaningful improvement (high certainty) of the urticaria activity score (UAS)7 (mean difference (MD) -5; 95%CI -7.75 to -2.25) and the itch severity score (ISS)7 (MD -2.15; 95% CI -3.2 to -1.1); does not increase (moderate certainty) quality of life (QoL) (Dermatology Life Quality Index (DLQI); MD -2.01; 95%CI -3.22 to -0.81); decreases (moderate certainty) rescue medication use (MD -1.68; 95%CI -2.95 to -0.4). Omalizumab 300 mg: results in clinically meaningful improvements (moderate certainty) of the UAS7 (MD -11.05; 95%CI -12.87 to -9.24), the ISS7 (MD -4.45; 95%CI -5.39 to -3.51), and QoL (high certainty) (DLQI; MD -4.03; 95% CI -5.56 to -2.5); decreases (moderate certainty) rescue medication use (MD -2.04; 95%CI -3.19 to -0.88) and drug-related serious AEs (RR 0.77; 95%CI 0.20 to 2.91).

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