



Omalizumab is Effective and Safe in the Treatment of Japanese Cedar Pollen-induced Seasonal Allergic Rhinitis

<http://www.firstlight.cn> 2006-12-18

Background: Seasonal allergic rhinitis (SAR) induced by Japanese cedar pollen is a substantial problem in Japan. Omalizumab, a novel humanized monoclonal anti-immunoglobulin E (IgE) antibody, has already been proven to reduce symptoms associated with SAR. We investigated the safety and efficacy of omalizumab in the treatment of patients with Japanese cedar pollen-induced SAR compared to placebo.

Methods: A randomized, placebo-controlled, double-blind study was conducted in 100 Japanese patients with a history of moderate-to-severe SAR induced by Japanese cedar pollens. Omalizumab (150, 225, 300, or 375mg) or placebo was administered subcutaneously every 2 or 4 weeks based on serum total IgE and body weight at baseline. The primary efficacy variable was the mean of daily nasal symptom medication scores (sum of the daily nasal symptom severity score and daily nasal rescue medication score) during the treatment period. Secondary efficacy variables included the daily ocular symptom medication score and related variables.

Results: Primary and all secondary efficacy variable scores were significantly lower in the omalizumab group than in the placebo group ($P < .01$). Serum free IgE levels markedly decreased in the omalizumab group and were associated with clinical efficacy. The overall incidence of injection site reactions was higher in the omalizumab group than in the placebo group; however, the adverse reaction profile was similar between the two groups when excluding injection site reactions. No anti-omalizumab antibodies were detected.

Conclusions: Omalizumab was effective and safe in the treatment of SAR induced by Japanese cedar pollen.

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