Abstract

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Efficacy of a House Dust Mite Sublingual Allergen Immunotherapy Tablet in Adults With Allergic Asthma: A Randomized Clinical Trial.

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Abstract

IMPORTANCE: The **house dust mite** (HDM) **sublingual allergen immunotherapy** (SLIT) **tablet** is a potential novel treatment option for HDM allergy-related **asthma**.

OBJECTIVES: To evaluate the **efficacy** and adverse events of the HDM SLIT **tablet** vs placebo for **asthma** exacerbations during an inhaled corticosteroid (ICS) reduction period.

DESIGN, SETTINGS, AND PARTICIPANTS: Double-blind, randomized, placebo-controlled trial conducted between August 2011 and April 2013 in 109 European trial sites. The trial included 834 **adults** with HDM allergy-related **asthma** not well controlled by ICS or combination products, and with HDM allergy-related rhinitis. Key exclusion criteria were FEV1 less than 70% of predicted value or hospitalization due to **asthma** within 3 months before randomization. **Efficacy** was assessed during the last 6 months of the trial when ICS was reduced by 50% for 3 months and then completely withdrawn for 3 months.

INTERVENTIONS: 1:1:1 randomization to once-daily treatment with placebo (n = 277) or HDM SLIT **tablet** (dosage groups: 6 SQ-HDM [n = 275] or 12 SQ-HDM [n = 282]) in addition to ICS and the short-acting β2-agonist salbutamol.

MAIN OUTCOMES AND MEASURES: Primary outcome was time to first moderate or severe **asthma** exacerbation during the ICS reduction period. Secondary outcomes were deterioration in **asthma** symptoms, change in **allergen**-specific immunoglobulin G4 (IgG4), change in **asthma** control or **asthma** quality-of-life questionnaires, and adverse events.

RESULTS: Among 834 randomized patients (mean age, 33 years [range, 17-83]; women, 48%), 693 completed the study. The 6 SQ-HDM and 12 SQ-HDM doses both significantly reduced the risk of a moderate or severe **asthma** exacerbation compared with placebo (hazard ratio [HR]: 0.72 [95% CI, 0.52-0.99] for the 6 SQ-HDM group, P = .045, and 0.69 [95% CI, 0.50-0.96] for the 12 SQ-HDM group, P = .03). The absolute risk differences based on the observed data (full analysis set) in the active groups vs the placebo group were 0.09 (95% CI, 0.01-0.15) for the 6 SQ-HDM group and 0.10 (95% CI, 0.02-0.16) for the 12 SQ-HDM group. There was no significant difference between the 2 active groups. Compared with placebo, there was a reduced risk of an exacerbation with deterioration in **asthma** symptoms (HR, 0.72 [95% CI, 0.49-1.02] for the 6 SQ-HDM group, P = .11, and 0.64 [95% CI, 0.42-0.96] for the 12 SQ-HDM group, P = .03) and a significant increase in **allergen**-specific IgG4. However, there was no significant difference for change in **asthma** control questionnaire or **asthma** quality-of-life questionnaire for either dose. There were no reports of severe systemic **allergic** reactions. The most frequent adverse events

were mild to moderate oral pruritus (13% for the 6 SQ-HDM group, 20% for the 12 SQ-HDM group, and 3% for the placebo group), mouth edema, and throat irritation.

CONCLUSIONS AND RELEVANCE: Among **adults** with HDM allergy-related **asthma** not well controlled by ICS, the addition of HDM SLIT to maintenance medications improved time to first moderate or severe **asthma** exacerbation during ICS reduction, with an estimated absolute reduction at 6 months of 9 to 10 percentage points; the reduction was primarily due to an effect on moderate exacerbations. Treatment-related adverse events were common at both active doses. Further studies are needed to assess long-term **efficacy** and safety.

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Comment in

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