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[Volume 124, Issue 3](#), Pages 471-477.e1
(September 2009)

◀ [previous](#) 22 of 54 [next](#) ▶

Early onset of action of a 5-grass-pollen 300-IR sublingual immunotherapy tablet evaluated in an allergen challenge chamber

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Background

The efficacy and safety of a 5-grass-pollen sublingual immunotherapy (SLIT) tablet (Stallergènes SA, Antony, France) have been evaluated in clinical studies during the pollen season. The allergen challenge chamber (ACC) has been developed as a pharmacodynamic assessment tool to control the environmental allergens and to avoid all problems associated with unpredictable pollen seasons.

Objective

We sought to evaluate the onset of action and efficacy of 300-IR (index of reactivity) SLIT tablets by using an ACC.

Methods

Patients with grass pollen–induced rhinoconjunctivitis were randomized into the active or placebo groups. A standardized allergen challenge with grass pollen and symptom evaluation every 15 minutes was performed at baseline, 1 week, and 1, 2, and 4 months of treatment. The primary end point was the average rhinoconjunctivitis total symptom score (ARTSS). Allergen-specific basophil activation, T-cell proliferation, and plasmatic IgE and IgG responses were assessed before and after treatment.

Results

In the intention-to-treat population (n = 89) a significant treatment effect was achieved after the first month ($P = .0042$) and second month ($P = .0203$) and was maintained through to the fourth month ($P = .0007$). In the active group the ARTSS (means \pm SDs) decreased at each challenge: week 1, 7.40 ± 2.682 ; month 1, 5.89 ± 2.431 ; month 2, 5.09 ± 2.088 ; and month 4, 4.85 ± 1.999 . An improvement (vs placebo) of 29.3% for the mean ARTSS (median, 33.3%) was observed at end point. Furthermore, the induction of grass pollen allergen–specific IgGs was associated with clinical response. The most frequent adverse reactions were local: oral pruritus, ear pruritus, and throat irritation.

Conclusions

▶ ABSTRACT
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In this ACC study the 300-IR 5-grass-pollen SLIT tablets had a significant effect on rhinoconjunctivitis symptoms (vs placebo) from the first month of treatment onward.

Key words: [Grass pollen](#), [tablets](#), [sublingual immunotherapy](#), [allergen challenge chamber](#), [Vienna Challenge Chamber](#)

Abbreviations used: [ACC](#), [Allergen challenge chamber](#), [AE](#), [Adverse event](#), [ARTSS](#), [Average rhinoconjunctivitis total symptom score](#), [IR](#), [Index of reactivity](#), [ITT](#), [Intention-to-treat](#), [PP](#), [Per-protocol](#), [RTSS](#), [Rhinoconjunctivitis total symptom score](#), [SAR](#), [Seasonal allergic rhinoconjunctivitis](#), [SLIT](#), [Sublingual immunotherapy](#), [TEAE](#), [Treatment-emergent adverse event](#), [VCC](#), [Vienna Challenge Chamber](#)

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