

Hay Fever in Kids Responds to Immunotherapy

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The 300-index of reactivity dose of 5-grass-pollen sublingual immunotherapy tablets resulted in a significant improvement in the rhinoconjunctivitis total symptom score in children and adolescents with pollen-related allergic rhinitis, results from a European multicenter study demonstrated.

A recent study of adults determined that the 300-index of reactivity tablet is the optimal dose of a 5-grass-pollen sublingual immunotherapy tablet (SLIT) for treating grass pollen-related rhinitis over the first pollen season (*J. Allergy Clin. Immunol.* 2007;120:1338-45). The current study, however, demonstrates that the identical dose is safe and effective in a pediatric population with a pre-seasonal regimen starting 4 months before the expected start of the pollen season and continued throughout the season.

The tablets are not marketed in the United States.

"This study demonstrates first-season efficacy in children and adolescents given pre-seasonal and co-seasonal specific immunotherapy, but this needs to be assessed in a long-term, placebo-controlled trial over several years," researchers led by Dr. Ulrich Wahn of Charité Hospital in Munich reported.

"Further studies are also needed to identify the optimal maintenance dose, and longer-term data are required to confirm whether SLIT will prevent progression from allergic rhinitis to asthma."

For the randomized, double-blind, placebo-controlled study, the researchers enrolled 278 children and adolescents aged 5-17 years at 29 centers in France, Spain, Germany, Poland, and Denmark. Each had grass pollen-related rhinoconjunctivitis for at least 2 years, as confirmed by a positive skin prick test and a timothy grass pollen-specific IgE level of at least class 2.

Of the 278 patients, 139 received once-daily SLIT tablets manufactured by Stallergenes of Antony, France, and 139 received placebo (*J. Allergy Clin. Immunol.* 2009;123:160-6). Treatment began 4 months prior to the estimated pollen season and continued throughout the season. The primary outcome measure was the rhinoconjunctivitis total symptom score (RTSS), which includes the six most common symptoms of pollinosis (sneezing, rhinorrhea, nasal pruritus, nasal congestion, ocular pruritus, and watery eyes).

The researchers reported that the mean treatment duration before pollen season was 113 days, while the mean treatment duration during pollen season was 39 days. Over that period, children in the treatment group experienced a statistically significant reduction in total rhinoconjunctivitis symptoms, as measured by the RTSS. Specifically, the improvement was 28% greater than that observed in the placebo group, for a median improvement of 39% during the pollen season.

"The level of improvement of mean RTSS compared with placebo exceeded the 20% threshold, which is suggested as the threshold for clinically relevant efficacy," the researchers noted. "This magnitude of effect is similar to that found in recent studies using SLIT tables in adult populations and occurred despite the use of rescue medication."

The mean rescue medication score was significantly reduced in the treat-

ment group, compared with the placebo group, for a median reduction of 49% during the pollen season.

Two patients in the treatment group and three patients in the placebo group had exacerbation of asthma, but none of the episodes was thought to be related to the study treatment.

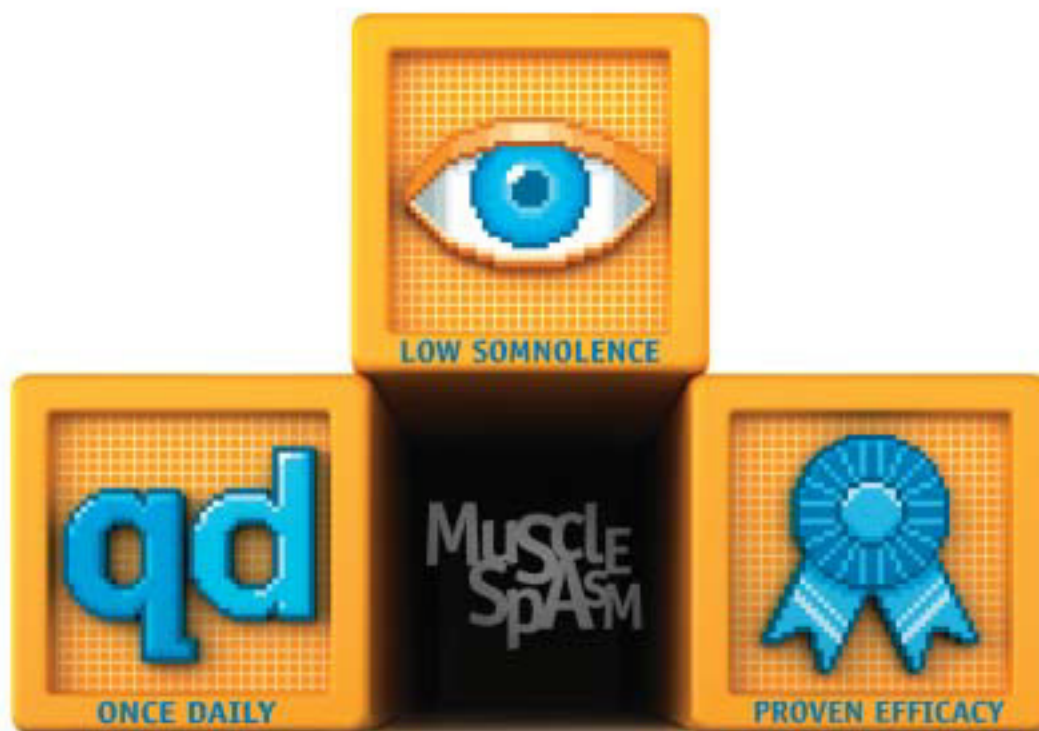
The researchers pointed out that children allergic only to grass pollens (monosensitized), as well as those sensi-

tive to grass pollens plus other allergens (polysensitized), were studied. Both groups showed evidence of comparable improvement.

The study was supported by Stallergenes. One of the study's seven authors disclosed that she has served as a consultant for and received research support from Stallergenes. Another disclosed that she has received honoraria and research support from the company. ■

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Reference: 1. Data on file. Studies 1105 and 1106. Cephalon, Inc.; 2004.



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