High-dose sublingual immunotherapy with single-dose aqueous grass pollen extract in children is effective and safe: a double-blind, placebo-controlled study.

Sublingual allergen-specific immunotherapy is a viable alternative to subcutaneous immunotherapy particularly attractive for use in children. This study investigated efficacy and safety of high-dose sublingual immunotherapy (SLIT) in children allergic to grass pollen in a randomized, double-blind, placebo-controlled trial. After a baseline seasonal observation, 207 children aged 4 to 12 years with grass pollen-allergic rhinitis/rhinoconjunctivitis with/without bronchial asthma (Global Initiative for Asthma I/II) received either high-dose grass pollen SLIT or placebo daily for 1 pre-/co-seasonal period. The primary end point was the change of the area under the curve of the symptom-medication score (SMS) from the baseline season to the first season after start of treatment. Secondary outcomes were well days, responders, immunologic changes, and safety. Mean changes in the area under the curve of the SMS from the
baseline to the first grass pollen season after the start of treatment were -212.5 for the active group and -97.8 for the placebo group (P = .0040). Rhinoconjunctivitis SMS (P = .0020) and separated symptom and medication scores were also statistically different between the 2 groups (P = .0121 and P = .0226, respectively). The number of well days and the percentage of responders were greater in the active group. Changes in allergen-specific IgE and IgG levels indicated a significant immunologic effect. The treatment was well tolerated, and no serious treatment-related events were reported. This study confirmed that this SLIT preparation significantly reduced symptoms and medication use in children with grass pollen-allergic rhinoconjunctivitis. The preparation showed significant effects on allergen-specific antibodies, was well tolerated, and appeared to be a valid therapeutic option in children allergic to grass pollen. This trial was registered at www.clinicaltrials.gov as NCT00841256.