

Conclusion

High dose hypoallergenic vaccination with Allergovit® Grasses is well documented.

Preseasonal courses of injections given in each of three successive years resulted in substantial improvement in symptom-medication scores and in overall rhinitis quality of life of the affected patients. The effect is long-lasting. Reductions in symptom-medication scores, asthma prevalence and onset of new sensitizations are still present for 6 up to 12 years after discontinuation of SCIT in previously treated patients.

Clinical Documentation

In a 2-year double blind placebo-controlled trial in 154 grass pollen allergic patients with rhinoconjunctivitis and/or asthma (GINA I or II) a difference in symptom-medication score (SMS) of 48.4% in favour of Allergovit® Grasses was revealed (see Fig. 1). Allergovit® Grasses also induced a 210-fold increase of grass pollen-specific IgG₄, clearly demonstrating its immunogenic activity. The median change in rhinitis quality of life (RQLQ according to Juniper et al., 1991) from baseline to the grass pollen season in the second year showed a statistically significant advantage for the active group. No serious adverse events were observed (Corrigan et al., 2005).

A third year of treatment even increased the positive effects. Compared with the first year the median AUC of SMS of the active group changed from 215 to 131 and the median of the overall RQLQ improved from 1.54 to 0.56 (Henzgen et al., WAC 2005).

The effect of Allergovit® Grasses continues. 6 years after cessation of a 3-year preseasonal grass pollen SIT in children the ex-SIT group showed lower SMS during the pollen season (see Fig. 2). Only 33% of patients with previous asthma experienced any further lower respiratory tract symptoms compared with 70% of the ex-control group. The need for asthma medication was significantly lower than for controls (Eng et al., 2002).

Data for both groups is now available for a period of 12 years after discontinuation of SIT. Still the SMS remains lower and there is a tendency for lower pollen asthma prevalence in the ex-SIT group. The percentage of new sensitizations to perennial allergens was 58% in the ex-SIT group compared to 100% in the ex-control group (Eng et al., submitted).

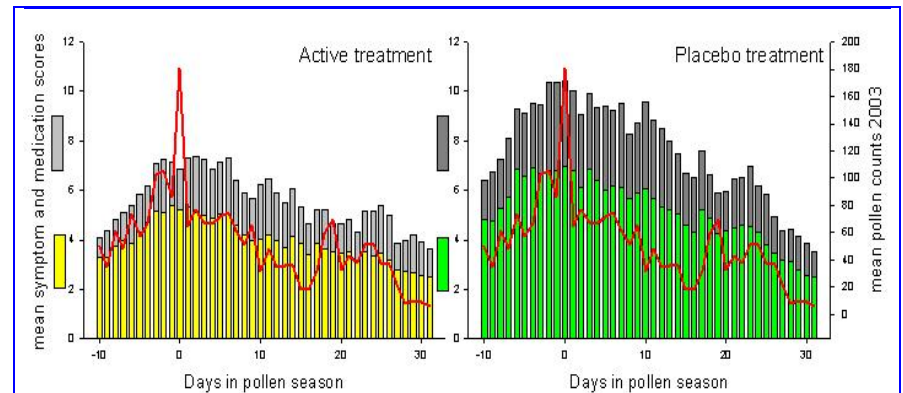


Fig 1: Combined symptom (yellow bars) and medication (grey bars) scores (SMS) and grass pollen counts during the pollen season of the second treatment period (2003). Mean values. Full analysis set (n = 143). Pollen counts – solid red line. The difference in SMS means (AUC) between active and placebo groups is 48.3% (Corrigan et al., 2005)

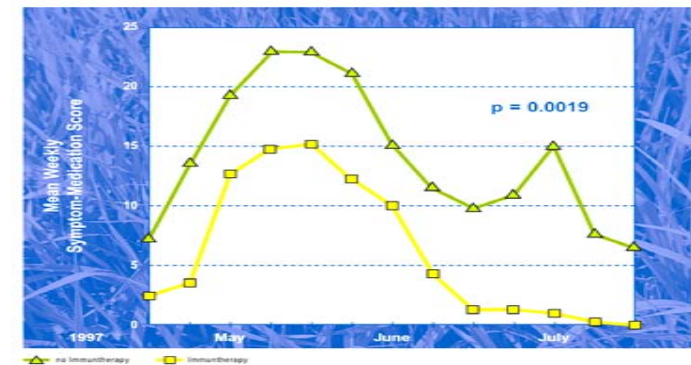


Fig 2: Total symptom-medication scores six years after cessation of SIT in children who previously received SIT (n = 13; yellow curve) or only symptomatic medication (n = 10; green curve) (Eng, 2002)

Allergopharma Policy

High dose hypoallergenic vaccination with Allergovit® Grasses achieves an optimal balance between strong efficacy and safety. Allergovit® Grasses is the first preparation with a proven positive effect prolonged for up to 12 years after cessation of SIT. Given in children it is not only delaying onset of new sensitizations and disease progression, but has the capacity to alter the course of allergic disease.

References:

Corrigan, C.J.; Kettner, J.; Doemer, C.; Cromwell, O.; Narkus, A. Efficacy and safety of preseasonal-specific immunotherapy with an aluminium-adsorbed six-grass pollen allergoid. *Allergy* 60: 801-807 (2005)

Eng, P.A.; Borer-Reinhold, M.; Heijnen, I.A.F.M.; Gnehm, H.P.E. 15—year follow-up of preseasonal grass-pollen immunotherapy in childhood (submitted)

Eng, P.A.; Reinhold, M.; Gnehm, H.P.E. Long-term efficacy of preseasonal grass pollen immunotherapy in children. *Allergy* 57: 306-312 (2002)

Henzgen, M.; Kettner, J.; Doemer, C.; Cromwell, O.; Narkus, A. Efficacious management of allergic rhinitis by three years of pre-seasonal specific immunotherapy with a grass-pollen allergoid (poster) (World Allergy Congress 2005, Munich)

Juniper, E.F.; Guyatt, G.H. Development and testing of a new measure of health status for clinical trials in rhinoconjunctivitis. *Clin Exp Allergy* 21: 77-83 (1991)

ALLERGOVIT® GRASSES

Composition:

Depot allergoids from grass pollen allergens for specific immunotherapy, adsorbed to aluminium hydroxide, preserved with phenol and suspended in physiological saline; water for injection. Standardization takes place in TU (therapeutic units). Strength A: 1,000 TU/ml, Strength B: 10,000 TU/ml.

Indications:

Allergic (IgE-mediated) diseases of inhalative origin occurring in adults and children from 6 years on induced by unavoidable allergens.

Contraindications:

Inflammation of the airways, persistent or insufficient treated asthma, irreversible changes in the reaction organ, inflammatory/febrile diseases, severe acute or chronic diseases (also malignant diseases), significant cardiovascular diseases which increase the risk of side effects from epinephrine, multiple sclerosis, diseases of the immune system (autoimmune diseases, immune complex-induced immunopathies, immune defects, etc.), active tuberculosis, severe psychological disorders, treatment with beta-blockers (local, systemic). Special caution in ACE-inhibitor therapy, poor compliance and pregnancy (treatment should not be started during pregnancy). Observe contraindications for epinephrine (adrenaline)! In the event of simultaneous vaccination observe intervals as directed.

Side effects:

Local and/or systemic reactions (up to anaphylactic shock) must be reckoned with, then stop injections immediately. Formation of granuloma, exacerbation of atopic eczema. Delayed local reaction as a visual immune response, fatigue (responsiveness!). The patient has to be kept under observation for at least 30 minutes after treatment. Side effects can occur even hours after treatment. On the day of the injection, physical exertion should be avoided.

Pharmaceutical form and pack sizes:

Suspension for subcutaneous injection: Pre-seasonal initial and maintenance treatment set: 2 vials of strength A and B with 3 ml each. Pre-seasonal and perennial maintenance treatment set: 1 vial strength B with 3 ml. For additional information on doses, administration etc. see package insert. In Germany only available on prescription.

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Allergopharma Medical Position Paper

High Dose Hypoallergenic Vaccination with Allergovit® Grasses: Short-Term Therapy – Long-Term Efficacy

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