**#0368** - Sublingual immunotherapy with a liquid birch pollen extract is similarly effective for younger and older patients with birch pollen induced allergic rhinitis/rhinoconjunctivitis

Pfaar, Oliver / Bachert, Claus / Kuna, Piotr / Panzner, Petr / Džupinová, Marika / Yu, Donghui / Mantikou, Eleni / Moed, Heleen / Klimek, L. / De Kam, Pieter Jan

**Introduction**
Allergic rhinitis/rhinoconjunctivitis (ARC) is an important problem worldwide and may significantly impair quality of life. Previously, a phase III study was conducted to establish the clinical efficacy and safety of pre- and co-seasonal sublingual immunotherapy (SLIT) with a liquid birch pollen extract for the treatment of birch pollen induced ARC. The primary analysis of this study showed a statistically significant and clinical relevant improvement on the primary efficacy endpoint: Combined Symptoms Medication Score (CSMS) during the birch pollen season after SIT compared to placebo (Pfaar et al. Allergy (2016); 71 (suppl.102): 45 (abstract 87)). The objective of this post-hoc analysis was to assess whether clinical efficacy of SLIT is similar for older (45-65 yrs) and younger (18-45 yrs) birch pollen allergic patients.
**Objectives**
The study was a randomized, double-blind, placebo-controlled, parallel-group study, with treatment with a liquid birch pollen extract (40,000 AUN/mL) starting at least 12 weeks before the birch pollen season and continuing during the birch pollen season (ClinicalTrials.gov NCT02231307), performed in 40 clinical study centers in 5 European countries. Study population consisted of 406 patients, 18-65 years of age, suffering from moderate to severe birch pollen induced ARC with or without mild to moderate controlled asthma.
For this post-hoc analysis, the effect of birch SLIT was assessed in all patients of the Intent-to-Treat group, i.e. 267 patients in the younger age group (age 18-45 years) and 90 patients in the older age group (age 45-65 years).
Clinical efficacy of Birch SLIT 40,000 AUN/mL was assessed by calculation of the difference in the CSMS as assessed during the birch pollen season compared to placebo for both sub-groups separately.
**Results**
A clinically relevant and statistically significant CSMS reduction was reached for both the older and younger age subgroups compared to placebo ($p=0.0013$ and $p=0.0022$, respectively). Moreover, in absolute terms the CSMS improvement was comparable in both subgroups and exceeded the pre-defined clinical relevant CSMS effect of 23% (relative difference of 40% and 28%, respectively).
**Conclusions**
Results of this post-hoc subgroup-analysis support the hypothesis that SLIT using a liquid birch pollen extract is similarly effective in older and younger birch pollen allergic patients, indicating that both age groups can benefit from this therapy to a similar extent.