#0813 - Sublingual immunotherapy with a liquid birch pollen extract is similarly effective in birch pollen allergic patients with high sensitization profile compared to patients with low sensitization profile

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 health 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. 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 compared to placebo (Pfaar et al. Allergy (2016); 71 (suppl.102): 45 (abstract 87)). The objective of this post-hoc analysis was to evaluate if birch pollen SLIT is similarly effective in patients with a high sensitization profile compared to patients with a low sensitization status.
Objectives
The study was a randomized, double-blind, placebo-controlled, parallel-group study, with treatment with 40,000 AUN/mL birch SLIT (ClinicalTrials.gov NCT02231307), performed in 40 clinical study centers in 5 European countries. In total, 406 patients, 18-65 years of age, suffering from moderate to severe birch pollen induced ARC were randomized.
The effect of SLIT was assessed in a subgroup of patients with high sensitization profile; defined as either birch specific SPT, NPT or IgE results in the upper 75% quartile compared to patients with a low sensitization profile (below the upper 75% quartile of all three diagnostic tests). The clinical efficacy of this liquid birch pollen extract (40,000 AUN/mL) for both sub-groups was assessed by the difference in the primary CSMS endpoint during the birch pollen season between the active vs. placebo treatment group using the Intent-to-Treat population.

Results
A clinically relevant and statistically significant CSMS reduction was reached for both the high and low birch sensitization subgroups compared to placebo ($p=0.0008$ and $p=0.0048$, 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 34% and 29%, respectively).
Conclusions
Results of this post-hoc subgroup-analysis support the hypothesis that SLIT with a liquid birch pollen extract is similarly effective in high and low birch pollen sensitized patients, indicating that patients with high and low sensitization status can benefit from this immune therapy to a similar extent.