#0812 - Early efficacy onset, already prior to the start of the birch pollen season, after sublingual immunotherapy with a liquid birch pollen extract

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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) 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 SLIT compared to placebo (Pfaar et al. Allergy (2016); 71 (suppl.102): 45 (abstract 87)). Considering allergen cross-reactivity and structural homology within the birch homologous tree group, the present post-hoc analysis aimed to evaluate whether the primary CSMS endpoint would reach statistical significance prior to measurement of the first positive birch pollen count.
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. CSMS was evaluated during the period 1 March 2015 until measurement of first positive birch pollen count.
Results
After treatment with birch SLIT, a clinically relevant and statistically significant 30.1% improvement in CSMS was observed compared to placebo($p=0.0021$), as measured in birch allergic patients prior to the appearance of the first birch pollen count.
Conclusions
The results of this post-hoc analysis support a beneficial effect of SLIT with a liquid birch pollen extract on allergic symptoms and medication, already visible prior to measurement of the first birch pollen count in birch allergic patients. These findings suggest an early onset of efficacy of this liquid SLIT birch pollen extract related to concomitant allergies for other early spring trees due to cross-reactivity and/or structural homology within the birch homologous tree group.