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Onset of action of loratadine/montelukast combination in subjects with seasonal allergic rhinitis in the environmental exposure unit

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Background

Onset of action is recognized as an important pharmacologic property of allergic rhinitis medications and can be reliably determined under the controlled conditions of the Environmental Exposure Unit (EEU).

Objective

To evaluate the onset of action of loratadine/montelukast (10 mg/10 mg) versus placebo in subjects with ragweed-induced seasonal allergic rhinitis (SAR).

Methods

A single-center, double-blind, parallel-group study of ragweed-sensitive allergic rhinitis subjects (N=310), performed in the EEU. Subjects were exposed to ragweed pollen in the EEU and symptoms were recorded at 30, 60, 90, and 120 minutes prior to a single dose of loratadine/montelukast or placebo. After dosing, symptoms were recorded for 4 hours - at 15-minute intervals for the first 2 hours and 30-minute intervals for the final 2 hours. The primary endpoint was the time to onset of action for loratadine/montelukast, defined as the first time point at which the mean change from baseline in total symptom score (TSS) for loratadine/montelukast became and remained significantly better than placebo. Secondary endpoints included nasal congestion scores and peak nasal inspiratory flow (PNIF).

Results

The onset of action of loratadine/montelukast for TSS was 1 hour 15 minutes (p=0.005 versus placebo). Loratadine/montelukast reduced nasal congestion as indicated by significant improvements in both the nasal congestion score (p=0.011) and PNIF measurements (p=0.007) within 1 hour 15 minutes post dose. The incidence of treatment-emergent adverse events was similar between groups.

Conclusion

The onset of action following treatment with loratadine/montelukast was 1 hour 15 minutes for TSS, as well as for nasal congestion. Loratadine/montelukast was well tolerated.

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