A Randomized, Multicenter, Double-blind, Phase III Study to Evaluate the Efficacy on Allergic Rhinitis and Safety of a Combination Therapy of Montelukast and Levocetirizine in Patients With Asthma and Allergic Rhinitis

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Accepted for publication April 30, 2018.
https://doi.org/10.1016/j.clinthera.2018.04.021
10149-2918/$ - see front matter

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ABSTRACT

Purpose: The aim of this study was to evaluate the efficacy and safety of a fixed-dose combination of montelukast and levocetirizine in patients with perennial allergic rhinitis with mild to moderate asthma compared with the efficacy and safety of montelukast alone.

Methods: This study was a 4-week, randomized, multicenter, double-blind, Phase III trial. After a 1-week placebo run-in period, the subjects were randomized to receive montelukast (10 mg/day, n = 112) or montelukast (10 mg/day)/levocetirizine (5 mg/day) (n = 116) treatment for 4 weeks. The primary efficacy end point was mean daytime nasal symptom score. Other efficacy end points included mean nighttime nasal symptom score, mean composite symptom score, overall assessment of allergic rhinitis by both subjects and physicians, forced expiratory volume in 1 second (FEV_1), forced vital capacity (FVC), FEV_1/FVC, asthma control test score, and the frequency of rescue medication used during the treatment period.

Findings: Of 333 patients screened for this study, 228 eligible patients were randomized to treatment. The mean (SD) age of patients was 43.32 (15.02) years, and two thirds of subjects were female (66.67%). The demographic characteristics were similar between the treatment groups. Compared with the montelukast group, the montelukast/levocetirizine group reported significant reductions in mean daytime nasal symptom score (least squares mean [SE] of combination vs montelukast, −0.98 [0.06] vs −0.81 [0.06]; $P = 0.045$). For all other allergic rhinitis efficacy end points, the montelukast/levocetirizine group showed greater improvement than the montelukast group. Similar results were observed in overall assessment scores and in FEV_1, FVC, FEV_1/FVC, and asthma control test score changes from baseline for the 2 treatment groups. Montelukast/levocetirizine was well tolerated, and the safety profile was similar to that observed in the montelukast group.

Implications: The fixed-dose combination of montelukast and levocetirizine was effective and safe in treating perennial allergic rhinitis in patients with asthma compared with montelukast alone. ClinicalTrials.gov identifier: NCT02552667. (*Clin Ther.* 2018;■:1−13) © 2018 The Authors. Published by Elsevier Inc.

Key Words: allergic rhinitis, asthma, clinical trial, fixed-dose combination, levocetirizine, montelukast.

INTRODUCTION

Rhinitis is an inflammation of the mucous lining of the nose, accompanied by symptoms that include rhinorrhea, sneezing, itching, nasal obstruction, and postnasal drip. Allergic rhinitis, an immunoglobulin E−mediated allergic inflammatory response caused by exposure to allergens, accounts for more than one half of all rhinitis cases and is observed in 10% to 50% of