



POSTER PRESENTATION

Open Access

Efficacy and safety of medium and high doses of mometasone furoate/formoterol (MF/F) combination treatment in subjects with severe persistent asthma

Steven F Weinstein^{1*†}, Kevin R Murphy², Jonathan Corren³, Hendrik Nolte⁴, Martha V White⁵

From Canadian Society of Allergy and Clinical Immunology Annual Scientific Meeting 2010
Victoria, Canada. 4-7 November 2010

Background

Multiple strengths of mometasone furoate/formoterol (MF/F) MDI combination therapy are under investigation as new treatments for asthma. We report efficacy/safety findings from a 3-month MF/F study in subjects with severe asthma.

Materials and methods

This was a 3-month, randomized, double-blind, parallel-group, multicenter study with a 2-3-week open-label, run-in period of mometasone furoate (MF) 400 µg twice-daily (BID). Subjects (≥12 years) were randomized to MF/F (200/10 µg or 400/10 µg BID) or MF (400 µg BID). The primary endpoint was the area under the curve (AUC) of the change in serial FEV₁ (0-12 hours) for MF/F 400/10 µg vs MF 400 µg from baseline to Week 12. Adverse events (AEs) and other clinical safety measures were recorded.

Results

A total of 728 subjects (mean: age = 47.9 y, asthma duration = 14.0 y, FEV₁ % predicted = 66.3, reversibility = 22.9%, Asthma Control Questionnaire [ACQ] score = 1.93) were randomized. Improvements in mean changes from baseline in FEV₁ AUC_{0-12 h} (L × h) at Week 12 were MF/F 200/10 µg = 3.59, MF/F 400/10 µg = 4.19, and MF 400 µg = 2.04, with both MF/F doses significantly better than MF (p < 0.001). These FEV₁s

correspond to average hourly increases of 0.30, 0.35, and 0.17 L, respectively. MF/F was associated with rapid (<5 min) and sustained improvement in lung function. The percentage of subjects experiencing asthma deterioration (ie, severe asthma exacerbation) was 12.4% (MF/F 200/10 µg), 12.2% (MF/F 400/10 µg), and 18.3% (MF 400 µg). There were no notable differences in AEs between the groups.

Conclusions

Both medium- and high-dose MF/F combination therapy led to significantly greater improvements in lung function compared with high-dose MF monotherapy in severe asthmatics.

Author details

¹Allergy and Asthma Specialists Medical Group and Research Center, Huntington Beach, CA, 92647, USA. ²Boys Town National Research Hospital, Boys Town, NE, 68130, USA. ³Allergy Medical Clinic, Research Division, Los Angeles, CA, 90025, USA. ⁴Merck Research Laboratories, Kenilworth, NJ, 07033, USA. ⁵Institute for Asthma and Allergy, Wheaton, MD, 20902, USA.

Published: 22 December 2010

doi:10.1186/1710-1492-6-S2-P34

Cite this article as: Weinstein et al.: Efficacy and safety of medium and high doses of mometasone furoate/formoterol (MF/F) combination treatment in subjects with severe persistent asthma. *Allergy, Asthma and Clinical Immunology* 2010 **6**(Suppl 2):P34.

* Correspondence: sfwocallergy.com

† Contributed equally

¹Allergy and Asthma Specialists Medical Group and Research Center, Huntington Beach, CA, 92647, USA

Full list of author information is available at the end of the article