



POSTER PRESENTATION

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Non-inferiority efficacy comparison of mometasone furoate/formoterol versus fluticasone propionate/salmeterol combination therapies in subjects with persistent asthma

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

Background

Mometasone furoate/formoterol (MF/F) combination therapy is a new treatment for persistent asthma. We report findings from a non-inferiority study that compared effects of MF/F and fluticasone propionate/salmeterol (FP/S) combination therapies on pulmonary function and onset of action in subjects with persistent asthma.

Materials and methods

This randomized, active-controlled, multicenter, non-inferiority trial enrolled subjects (≥ 12 yrs) previously treated with medium-dose inhaled corticosteroid alone or combined with a long-acting β_2 -agonist. Following a 2-4 wk run-in treatment period with MF administered via metered-dose inhaler (MDI) 200 μg twice daily (BID), eligible subjects were randomized to MF/F-MDI 200/10 μg BID or FP/S administered via dry-powder inhaler (DPI) 250/50 μg BID for 12 wks. The primary endpoint was change from baseline in area under the curve in forced expiratory volume in 1 s 0-12 h post-dose ($\text{FEV}_1\text{AUC}_{0-12\text{ h}}$). Key secondary endpoints included onset of action, defined as change from baseline in FEV_1 at 5 min postdose on Day 1.

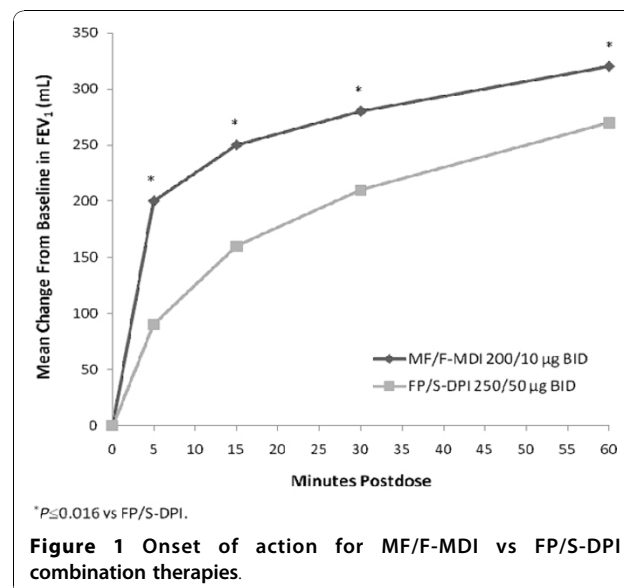
Results

722 subjects were randomized to MF/F-MDI ($n = 371$) or FP/S-DPI ($n = 351$). MF/F-MDI was found to be non-inferior to FP/S-DPI for mean $\text{FEV}_1\text{AUC}_{0-12\text{ h}}$ at

endpoint (3.43 vs 3.24 Lxh, respectively; 95% CI, -0.40, 0.76). MF/F-MDI's onset of action was rapid and significantly faster than observed for FP/S-DPI (Figure 1), with a 200 mL mean increase from baseline in FEV_1 at 5 min postdose (first scheduled measurement) on Day 1 for MF/F-MDI vs 90 mL for FP/S-DPI ($P < 0.001$).

Conclusions

This non-inferiority trial demonstrated that MDI-administered MF/F 200/10 μg BID was non-inferior to DPI-administered FP/S 250/50 μg BID in $\text{FEV}_1\text{AUC}_{0-12\text{ h}}$. MF/F-MDI was superior to FP/S-DPI in onset of action.



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Published: 22 December 2010

doi:10.1186/1710-1492-6-S2-P33

Cite this article as: Bernstein *et al.*: Non-inferiority efficacy comparison of mometasone furoate/formoterol versus fluticasone propionate/salmeterol combination therapies in subjects with persistent asthma. *Allergy, Asthma and Clinical Immunology* 2010 **6**(Suppl 2):P33.

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