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POSTER PRESENTATION Open Access

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

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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

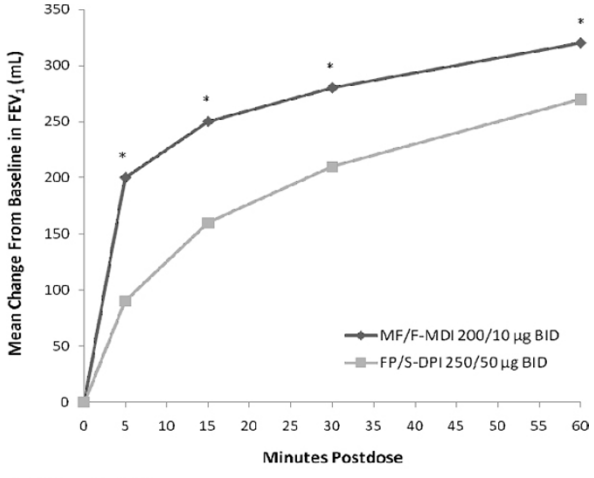
This randomized, active-controlled, multicenter, non-inferiority trial enrolled subjects (≥12 yrs) previously treated with medium-dose inhaled corticosteroid alone or combined with a long-acting β_2-agonist. Following a 2-4 wk run-in treatment period with MF administered via metered-dose inhaler (MDI) 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 postdose ($FEV_1AUC_{0\text{-}12\ h}$). 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 $FEV_1AUC_{0\text{-}12\ h}$ 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 $FEV_1AUC_{0\text{-}12\ h}$. MF/F-MDI was superior to FP/S-DPI in onset of action.



*$P \leq 0.016$ vs FP/S-DPI.

Figure 1 Onset of action for MF/F-MDI vs FP/S-DPI combination therapies.

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