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

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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 FEV_1 (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, FEV_1 % predicted = 66.3, reversibility = 22.9%, Asthma Control Questionnaire [ACQ] score = 1.93) were randomized. Improvements in mean changes from baseline in FEV_1 $AUC_{0\text{-}12\ h}$ (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 FEV_1s 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.

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