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Efficacy and safety of combined medium-dose mometasone furoate/formoterol (MF/F) in persistent asthmatics

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Background

The availability of controller therapies at multiple strengths is important to treat different severities of asthma (NHLBI and GINA guidelines). The clinical effect of medium-dose mometasone furoate/formoterol (MF/F) combination administered via single inhaler had never been characterized in asthmatic subjects versus placebo. We investigated the effect of medium-dose MF/F administered via an MDI on asthma deteriorations (ie, severe asthma exacerbations) and pulmonary function in moderately-severe asthmatics inadequately-controlled on medium-dose inhaled corticosteroids (ICS) ± long-acting β_2-agonists (LABA).

Materials and methods

After 2-3-weeks open-label run-in with MF 200μg BID, subjects (≥12 years) were randomized to 26-weeks treatment BID with MF/F 200/10μg, MF 200μg, F 10μg, or placebo. Coprimary endpoints were time-to-first asthma deterioration over the treatment period (MF/F vs F), and the area under the curve (AUC) of the change in serial FEV_1 [0-12 hr] to Week 12 (MF/F vs MF).

Results

781 subjects (mean: age=42.4 y, asthma duration=16.07 y, FEV_1 % predicted=72.62%, reversibility=18.80%, ACQ score=1.51) were randomized. MF/F increased the time-to-first asthma deterioration and decreased the proportion of subjects who experienced asthma deteriorations (MF/F=30.4%; MF=33.9% [p=0.565]; F=54.0% [p<0.001]; placebo=55.6% [p<0.001]). MF/F treatment improved lung function more than MF within 5 minutes following administration (p<0.001); mean Week-12 $FEV_1AUC_{0\text{-}12h}$ (L x h over baseline): MF/F=3.11, MF=1.30, F=1.93, and placebo=0.57 (effect was maintained throughout the treatment period). Adverse events were rare and similar across treatment groups.

Conclusions

MF/F 200/10μg was more effective in reducing asthma deteriorations and improving lung function in asthmatics uncontrolled on medium-dose ICS±LABA than placebo, MF or F.

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