



MEETING ABSTRACT

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Effect of mometasone furoate/formoterol combination therapy on nocturnal awakenings in subjects with persistent asthma

David Pearlman^{1*}, Robert Nathan², Eli Meltzer³, Hendrik Nolte⁴, Steven Weinstein⁵

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Objective

We characterized the effect of mometasone furoate/formoterol (MF/F) treatment on nocturnal awakenings requiring rescue-medication (SABA) use in three Phase III efficacy trials (baseline=awakenings in wk prior to first dose; endpoint=awakenings across entire treatment period).

Methods

Subjects were asthmatics previously using low- (n=746), medium- (n=781) or high-dose (n=728) inhaled corticosteroids ICS. Low-dose subjects were randomized to 26-wk treatment with MF/F 100/10 μ g, MF 100 μ g, F 10 μ g, or placebo; medium-dose subjects to 26-wk treatment with MF/F 200/10 μ g, MF 200 μ g, F 10 μ g, or placebo; high-dose subjects to 12-wk treatment with MF/F 400/10 μ g, MF/F 200/10 μ g, or MF 400 μ g. All treatments were delivered twice-daily via metered-dose inhaler.

Results

Baseline awakenings ranged from 0.84–1.05 (MF/F 100/10 μ g study), 1.05–1.26 (MF/F 200/10 μ g study), and 1.33–1.61 nights/wk (MF/F 400/10 μ g and 200/10 μ g study). Nocturnal awakenings were reduced by MF/F 100/10 μ g=–0.42, MF 100 μ g=–0.21, F 10 μ g=–0.21, and placebo=0.14 nights/wk; changes in the other placebo-controlled study were MF/F 200/10 μ g=–0.56, MF 200 μ g=–0.35, F 10 μ g=+0.07 and placebo=0.00 night/wk, respectively. In both of these studies MF/F was superior to placebo ($P<.001$) and F ($P=.035$); MF was also superior to F and placebo. In the non-placebo controlled study, awakenings were reduced

by –0.70, –0.70 and –0.35 nights/week by MF/F 200/10 μ g, MF/F 400/10 μ g and MF 400 μ g, respectively; both MF/F treatments were superior to MF ($P\leq.006$).

Conclusions

Both MF/F and MF significantly reduced nocturnal-awakenings compared with F and placebo. Both doses of MF/F were superior to MF in the non-placebo controlled study.

Author details

¹Colorado Allergy and Asthma Centers, P.C., Denver, CO, USA. ²Asthma and Allergy Associates and Research Center, Colorado Springs, CO, USA. ³Allergy and Asthma Medical Group and Research Center, San Diego, CA, USA. ⁴Merck Research Laboratories, Kenilworth, NJ, USA. ⁵Allergy & Asthma Specialists Medical Group, Huntington Beach, CA, USA.

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¹Colorado Allergy and Asthma Centers, P.C., Denver, CO, USA
Full list of author information is available at the end of the article