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Title: Bronchodilation with mometasone furoate/formoterol fumarate administered by metered-dose inhaler with and without a spacer in children with persistent asthma

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Body: Rationale: The bronchodilatory effect of mometasone furoate/formoterol fumarate (MF/F) administered by metered-dose inhaler (MDI) with or without spacer has not been evaluated previously in children. Methods: This was a randomized, multicenter, placebo (PBO)-controlled, single-dose 4-period crossover study. Children with persistent asthma aged 5-11y participated in this study. Subjects used inhaled corticosteroids with/without long-acting beta-2 agonists for ≥ 12 wk before enrollment, and at screening had FEV₁ $\geq 70\%$ predicted. Subjects received MF/F-MDI 100/10 μ g with/without spacer, F-DPI 10 μ g, and PBO-MDI with/without spacer in separate treatment periods. The primary endpoint was FEV₁ AUC (0-12 h) for the comparison of MF/F with spacer vs PBO. Secondary measurements included MF/F without spacer vs PBO, as well as MF/F with spacer vs MF/F without spacer, and F-DPI vs PBO. Analysis was performed with an ANCOVA model for a crossover study. Results: Data from 87 subjects were analyzed. MF/F with spacer demonstrated a larger change in mean FEV₁ AUC (0-12h) vs PBO (115 vs -9mL), with a treatment difference of 124mL (95% CI 94 to 154, P<.001). Similarly, MF/F without spacer vs PBO resulted in a 102mL difference in mean adjusted FEV₁ AUC_{0-12h} (95% CI 73 to 131, P<.001), whereas the difference between MF/F with spacer vs MF/F without spacer was 22 mL (95% CI -8 to 52, P=.144). The difference between F-DPI vs PBO was 106 mL (95% CI 77 to 135, P<.001). No unexpected adverse events were observed. Conclusions: In this trial, MF/F-MDI 100/10 μ g demonstrated significant bronchodilation in children aged 5-11y regardless of the use of a spacer.