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Title: Efficacy of fluticasone furoate (FF) as a monotherapy and in combination with vilanterol (VI) over 12 weeks in patients with persistent asthma

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Body: Introduction: The inhaled corticosteroid FF in combination with the long-acting beta$_2$ agonist VI is under development for the treatment of asthma and COPD. Objectives: To compare the efficacy and safety of FF/VI and FF in patients (aged ≥12 years) with persistent asthma. Methods: In a randomised, double-blind, parallel-group study, patients (N=609; ITT) received FF/VI 100/25mcg, FF 100mcg or placebo once daily in the evening via a new dry powder inhaler. Co-primary endpoints: change from baseline in trough FEV_1 and weighted mean (wm) 0–24h FEV_1. Rescue-free 24h periods and safety were also assessed. Results: Placebo increased trough FEV_1 (196mL) and $wmFEV_1$ (212mL) vs baseline. FF/VI and FF, respectively, significantly improved compared with placebo trough FEV_1 (172mL [p<0.001] and 136mL [p=0.002]) and $wmFEV_1$ (302mL [p<0.001] and 186mL [p=0.003]). Treatment differences between FF/VI and FF approached significance for $wmFEV_1$ (116mL, p=0.060), but not trough FEV_1 (36mL, p=0.405). Percent of rescue-free 24h periods with FF/VI was 10.6% greater than FF and 19.3% greater than placebo. Statistically significant (p=0.032) urinary cortisol suppression was seen with FF/VI (ratio=0.82) relative to placebo, but not FF. Adverse event and safety profiles were similar across treatment groups. Conclusions: Significant improvement in lung function was observed with FF/VI and FF in patients with persistent asthma. Addition of VI to FF did not significantly improve FEV_1, but a numerical increase was seen. The high placebo response in evening trough FEV_1 may have influenced the assessment of efficacy in this study. Funded by GSK (HZA106827; NCT01165138).