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Title: The efficacy of inhaled fluticasone furoate (FF) and vilanterol (VI) administered in combination in asthma is comparable when administered in the morning or evening

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Body: Introduction: The novel corticosteroid FF and long-acting beta$_2$ agonist VI combination (FF/VI) is being developed as a once-daily inhaled treatment for asthma and COPD. Objectives: To investigate the effect of time of day of dosing (AM or PM) on the efficacy of FF/VI (100/25mcg). Methods: Single centre, randomised, double-blind, placebo-controlled, three-way crossover study. Subjects with persistent asthma [N=26; 24–64 years] received FF/VI (AM or PM) or matching placebo (P) once daily for 14(±2) days. FEV_1 (0–24h weighted mean and pre-treatment [AM and PM]) was determined after the Day 14 PM dose together with pre-treatment [AM and PM] PEF on Days 1–12. Results: FF/VI administered AM or PM produced clinically significant increases in weighted mean FEV_1: the differences [95% CI] from P were 377mL [293, 462] and 422mL [337, 507], respectively; the difference between AM and PM dosing was –44mL [–125, 36]. Pre-treatment AM FEV_1 differences [95% CI] from P were 403mL [272, 533] and 496mL [369, 624] after AM and PM dosing, respectively; the treatment difference was –94mL [–221, 34]. Pre-treatment PM FEV_1 differences [95% CI] from P were 275mL [169, 380] and 309mL [205, 413] after AM and PM dosing, respectively; the treatment difference was –34mL [–138, 70]. FF/VI (AM or PM) produced rapid increases in PEF with the full effect apparent after the first dose and maintained throughout the 14 day treatment period. Conclusion: The efficacy of FF/VI (100/25mcg) was comparable when dosed in the morning or evening in subjects with persistent asthma. Funded by GSK (HZA114624; NCT01287065).