P111 FLUTICASONE PROPIONATE/FORMOTEROL FUMARATE COMBINATION THERAPY IS SUPERIOR TO FLUTICASONE PROPIONATE ALONE IN IMPROVING ASTHMA CONTROL

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Introduction and Objectives Poor asthma control impacts on patients' health and reduces their quality of life. Despite a rise in the proportion of patients receiving treatment, asthma remains uncontrolled in many patients. A new therapy option combining the inhaled corticosteroid fluticasone propionate (FLUT) with the long-acting ß$_2$-agonist formoterol fumarate (FORM) in a single aerosol inhaler (FLUT/FORM; ***flutiform***®) has been developed for the treatment of asthma. This integrated analysis of data from five randomised, double-blind, parallel-group phase 3 studies assessed the effects of FLUT/FORM compared with FLUT alone on the percentage of asthma control days.

Methods Symptomatic adult and adolescent patients with mild, moderate or severe asthma were randomly assigned to receive FLUT/FORM (100/10, 250/10 or 500/20 µg twice daily) or the equivalent nominal dose of FLUT alone (100, 250 or 500 µg twice daily) for 8 or 12 weeks. Most patients randomised to treatment had uncontrolled asthma. The percentage change in asthma control days (defined as those with no use of rescue medication, an asthma symptom score reporting no symptoms and a sleep disturbance score indicating that the patient slept through the night) was assessed from baseline to study end.

Results At baseline, the percentage of asthma control days was low in both groups (FLUT/FORM [n=623]: 12.8%; FLUT [n=623]: 12.6%). FLUT/FORM combination therapy was superior to FLUT alone for improvement in percentage of asthma control days. At study end, patients in the FLUT/FORM group experienced a mean of 62.4% asthma control days, an improvement of 49.6% from baseline, whereas FLUT treatment was associated with 54.8% asthma control days (42.2% change from baseline). FLUT/FORM provided a statistically significant improvement in asthma control days compared with FLUT alone (least-squares mean difference [95% CI]: 7.5% [3.21 to 11.84]; p<0.001).

Conclusions Fluticasone/formoterol combination therapy is superior to fluticasone monotherapy for improving the percentage of asthma control days over 8 or 12 weeks' treatment in adults and adolescents with mild, moderate or severe asthma. These data suggest the combination of fluticasone and formoterol in a single aerosol inhaler will provide an effective option for asthma maintenance therapy.

P112 FLUTICASONE PROPIONATE/FORMOTEROL FUMARATE COMBINATION THERAPY REDUCES THE RISK OF EXACERBATIONS COMPARED WITH ITS INDIVIDUAL COMPONENTS IN PATIENTS WITH ASTHMA

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Introduction and Objectives Asthma remains uncontrolled in many patients, as indicated by exacerbations, deteriorating symptoms and impaired quality of life. A new option has been developed for the maintenance treatment of asthma, combining the inhaled corticosteroid fluticasone propionate (FLUT) with the long-acting ß$_2$-agonist formoterol fumarate (FORM) in a single aerosol inhaler (FLUT/FORM; ***flutiform***®). A pooled analysis of data from up to five randomised, double-blind, parallel-group phase 3 studies assessed the effects of FLUT/FORM on asthma exacerbations.

Methods Adults and adolescents with mild, moderate or severe asthma were randomised to FLUT/FORM (100/10, 250/10 or 500/20 µg twice daily), the equivalent nominal dose of FLUT monotherapy (100, 250 or 500 µg twice daily; five studies) or FORM monotherapy (10 µg twice daily; three studies) for 8 or 12 weeks. The endpoints assessed were time to first exacerbation and proportion of patients experiencing an exacerbation. Exacerbations were defined as peak expiratory flow rate >30% below baseline, awakening at night due to asthma, use of rescue medication 3–4 times per day (each on =2 consecutive days; mild-to-moderate exacerbation), need for additional therapy, or emergency visit or hospitalisation due to asthma (severe exacerbation).

Results Time to first exacerbation (any severity) was significantly longer with FLUT/FORM (n=641) than with FLUT (n=643; p=0.01). Similarly, time to first exacerbation was significantly longer with FLUT/FORM (n=341) than FORM (n=345; p<0.001). Overall, the proportion of patients with any exacerbation was significantly lower with FLUT/FORM (18.2%) than with FORM (31.3%; p<0.001). Fewer patients experienced severe exacerbations with FLUT/FORM than FORM alone (FLUT/FORM 2.4%; FORM 9.6%; p<0.001). Similarly, fewer patients experienced any exacerbation with FLUT/FORM (26.8%) than with FLUT (32.8%; p=0.02) and fewer patients experienced severe exacerbations with FLUT/FORM than FLUT alone (FLUT/FORM 1.9%; FLUT 2.8%; p=0.36).

Conclusions Fluticasone/formoterol significantly reduces the risk of asthma exacerbations compared with its individual components. Combination therapy with fluticasone and formoterol in a single aerosol inhaler may help to improve asthma control and reduce the risk of asthma exacerbations that can impair patients' quality of life.

P113 THE COST-EFFECTIVENESS OF STEP DOWN FROM HIGH DOSE FLUTICASONE/SALMETEROL DRY POWDER OR SUSPENSION FORMULATIONS IN ASTHMA APPLIED TO THE UK SETTING

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Objectives The stepwise management of asthma outlined in the BTS/SIGN guideline recommends stepping down asthma patients where control is achieved. The aim of this analysis was to estimate the costs and health outcomes associated with step down of controlled patients on high dose fluticasone/salmeterol (FP/S 1000/100 µg daily) to either extrafine beclometasone/formoterol (BDP/F 400/24 µg) pMDI or medium dose FP/S (500/100 µg) dry powder in the UK setting.

Methods A patient-level simulation Markov model was constructed to enable the simulation of a cohort of patients through three comparative arms (FP/S 1000/100, FP/S 500/100, BDP/F 400/24). Transition probabilities and healthcare resources costs were derived from a recent multinational clinical trial comparing BDP/F 400/24 µg vs FP/S 500/100 µg as step down therapy in asthma. Direct costs and health state utilities were sourced from UK costs and published literature. The cost of FP/S 1000/100 was calculated considering the dry powder formulation. An additional analysis was conducted considering the suspension formulation. The analysis was conducted from a UK health system perspective, based on 6 months horizon. Probabilistic sensitivity analyses were conducted.