In patients with asthma, is budesonide (BUD) plus formoterol (FORM) (BUD+FORM) both for maintenance and symptom relief more effective than fixed dosing using BUD+FORM plus a short acting β2 agonist (SABA) or a 4 fold higher dose of BUD plus SABA for reducing the rate of severe asthma exacerbations?

**METHODS**

**Design:** randomised controlled trial.

**Allocation:** concealed.*

**Blinding:** blinded (patients and healthcare providers).*

**Follow up period:** 1 year.

**Setting:** 246 centers in 22 countries

**Patients:** 2,760 outpatients 4–80 years of age (mean age 36 y, 55% female; 12% children 4–11 y of age) with asthma who were using inhaled corticosteroids.

**Intervention:** BUD+FORM (budesonide, 80 μg, plus formoterol, 4.5 μg) both for maintenance and as needed (BUD+FORM for both, n = 925), BUD+FORM for maintenance plus terbutaline, 0.4 mg as needed (BUD+FORM plus SABA, n = 909), or budesonide high dose 320 μg for maintenance plus terbutaline as needed (BUDH plus SABA, n = 926). All maintenance treatments were twice daily for patients 12–80 years of age and once daily for children 4–11 years of age.

**Outcomes:** time to first severe exacerbation (defined as deterioration in asthma resulting in hospital admission or emergency room treatment, oral steroid treatment, or morning peak expiratory flow <70% of baseline on 2 consecutive d).

**Patient follow up:** 99.2% of patients were included in the intention to treat analyses.

*See glossary.

**MAIN RESULTS**

Time to first severe exacerbation was greater in the BUD+FORM for both group than in the BUD+FORM plus SABA group or BUDH plus SABA group had >1 severe asthma exacerbation (table).

**CONCLUSION**

In patients with asthma, budesonide plus formoterol (BUD+FORM) both for maintenance and symptom relief was more effective than fixed dosing using BUD+FORM plus a short acting β2 agonist (SABA) or a 4 fold higher dose of budesonide plus SABA.

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