Maintenance and symptom relief with budesonide plus formoterol reduced severe asthma exacerbations


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

CONCLUSION

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

A modified version of this abstract appears in Evidence-Based Medicine.

TREATMENT

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

METHODS

Design: randomised controlled trial.
Allocation: concealed.
Blinding: concealed (patients and healthcare providers).
Follow up period: 1 year
Setting: 246 centres in 22 countries.

Patients: 2760 outpatients (mean age 36 y, 55% women/girls; 12% children 4–11 y) with asthma who were using inhaled corticosteroids (ICSs).

Intervention: BUDFORM (BUD, 80 µg plus FORM, 4.5 µg) both for maintenance and as needed (BUDFORM for all, n = 925); BUDFORM for maintenance plus terbutaline, 0.4 mg as needed (BUDFORM plus SABA, n = 909); or BUD, 320 µg, plus terbutaline (BUD 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 asthma exacerbation (deterioration in asthma resulting in hospital admission or emergency department treatment, oral steroid treatment, or morning peak expiratory flow <70% of baseline on 2 consecutive days).

Patient follow up: 99.7% of patients were included in the intention to treat analyses.

MAIN RESULTS

Time to first severe exacerbation was longer in the BUDFORM-for-all group than in the BUDFORM plus SABA group or BUD plus SABA group (p values <0.001). Fewer patients in the BUDFORM-for-all group (p values <0.001) had >1 severe asthma exacerbation (table).

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<table>
<thead>
<tr>
<th>Outcome at 1 year</th>
<th>Comparisons</th>
<th>Event rates</th>
<th>RRR (95% CI)</th>
<th>NNT (CI)</th>
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</thead>
<tbody>
<tr>
<td>&gt;1 severe asthma exacerbation</td>
<td>BUDFORM for all v BUDFORM plus SABA</td>
<td>16% v 27%</td>
<td>41% (30 to 52)</td>
<td>10 (8 to 13)</td>
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<tr>
<td></td>
<td>BUDFORM for all v BUD plus SABA</td>
<td>16% v 28%</td>
<td>43% (31 to 53)</td>
<td>9 (7 to 12)</td>
</tr>
</tbody>
</table>

*Abbreviations defined in glossary; RRR, NNT, and CI calculated from Cox proportional hazard ratios in article.