The inactivated trivalent split-virus influenza vaccine was safe in stable asthma


**Main Results**

Analysis was by intention to treat. The rates of exacerbations of asthma within 14 days after vaccine or placebo injections did not differ (Table). The exacerbation rates were also similar in groups of patients defined according to age and severity of asthma. More patients reported body aches after the vaccine than after the placebo injection (25% vs 21%, P < 0.001). The vaccine and placebo injections did not differ for other secondary outcomes.

**Conclusion**

In patients with stable asthma, the inactivated trivalent split-virus influenza vaccine was as safe as placebo.

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*See Glossary.

**Incidence of asthma exacerbations 14 days after vaccine and placebo injections**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of patients</th>
<th>Vaccine injection</th>
<th>Placebo injection</th>
<th>Absolute difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exacerbations</td>
<td>1952</td>
<td>28.8%</td>
<td>27.7%</td>
<td>1.1% (-1.4 to 3.6)‡</td>
</tr>
</tbody>
</table>

†Exacerbations = new or increased use of oral corticosteroids, unscheduled use of health care for asthma symptoms, increased use of rescue medication, or 30% decrease in peak expiratory flow rate (PEFR) from the second-highest morning PEFR measured during the study.

‡Not significant.

**Commentary**

In patients with asthma, infection with influenza can lead to bronchoconstriction and serious asthma exacerbations. Infection is a common reason for hospitalization in children with asthma (1). Although immunization is effective in reducing exacerbations in patients with chronic obstructive pulmonary disease (2), concern has been raised about the role of immunization in patients with asthma. In a recent review (3), it was suggested that the lack of evidence of benefit and the potential harm associated with influenza immunization indicated the need for a cautious interpretation of the current guidelines, which include a consensus recommendation to immunize patients with asthma. A large randomized controlled trial was also recommended (3).

The study by the ALAACRC group is therefore welcome news. This large, multicentered, double-blind trial with a crossover design studied patients with stable asthma who were immunized against influenza with the inactivated trivalent split-virus vaccine. The investigators used rigorous methods and assessed patients for important clinical outcomes (i.e., exacerbations) and pulmonary function for up to 14 days. Overall, the results of this study indicate that influenza vaccination in adults and children with stable asthma is safe. However, myalgia seems to be a common adverse effect and patients should be warned accordingly. The study firmly supports the safety of vaccination for patients with asthma, and efforts should be made to increase immunization in this group.

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**References**

