

To the Editors:

## Salmeterol multicentre asthma research trial (SMART): interim analysis shows increased risk of asthma related deaths

We refer to the paragraph with the above caption in the *Ceylon Medical Journal* 2003; 48: 30. This summary does not give a complete picture of the findings of the study.

We would like that the following be added. "The interim analysis did not show a statistically significant result for the primary endpoint – a combination of respiratory related deaths or intubations (or ventilatory failure). There was a trend, however, towards increases in asthma related deaths and serious asthma episodes when all patients in the study were considered, though again this did not reach statistical significance. A further analysis of the data suggested that the risk may be greater in African-American patients. Also, further analyses showed

that patients not taking inhaled steroids at study entry appeared to have a greater risk for serious outcomes than those who were taking inhaled corticosteroids" (1).

FDA emphasises that based on available data, the benefits of salmeterol (Serevent) for the asthma population continue to outweigh the risks and that the serious adverse events reported in the trial were rare (1). The SMART study reiterates the recommendation that salmeterol should not be prescribed alone. It should always be combined with an inhaled corticosteroid.

### Reference

1. Study of asthma-drug halted. U.S. Food and Administration. FDA Talk Paper January 23, 2003.

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