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## LUNG ALERT .....

### Combination treatment may help patients with COPD, but does not improve mortality

▲ Calverley PM, Anderson JA, Celli B. Salmeterol and fluticasone propionate and survival in chronic obstructive disease. *N Engl J Med* 2007;**356**:775–89.

This multicentre, randomised, double blind trial comparing the combination of salmeterol and fluticasone propionate 50/500µg twice daily with placebo, salmeterol alone or fluticasone alone was carried out over a period of 3 years. Subjects included current or ex-smokers with at least a 10-pack year history, a diagnosis of chronic obstructive pulmonary disease (COPD) and a prebronchodilator forced expiratory volume in 1 s (FEV<sub>1</sub>) of less than 60% predicted. There were four treatment groups into which the 6184 patients were randomised.

All-cause mortality rates (the primary outcome) were 12.6% in the combination group, 15.2% in the placebo group, 13.5% in the salmeterol group and 16.0% in the fluticasone group. The absolute risk reduction for death in the combination treatment group compared with the placebo group was 2.6% but this did not reach statistical significance (p = 0.052).

There was an increased incidence of pneumonia in the fluticasone propionate treatment regimes (19.6% in the combination group, 18.3% in the fluticasone group, 13.3% in the salmeterol group and 12.3% in the placebo group; p<0.001 for comparison between both combination treatment and fluticasone groups and the placebo group) but this did not translate to an increase in the number of deaths.

The high dropout rate in the placebo group may well have led to a loss of sensitivity of the data as these patients may then have gone on to active treatment, making it more difficult to detect superiority of the active treatment arm.

The TORCH study provides us with important data on the natural progression of COPD. However, although the salmeterol–fluticasone combination failed to demonstrate an improvement in mortality according to the predefined statistical criteria, it did show significant improvements in exacerbation rates, health status and lung function.

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