Efficacy and safety of aclidinium/formoterol versus salmeterol/fluticasone: a phase 3 COPD study

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Abstract

The efficacy and safety of twice-daily aclidinium bromide/formoterol fumarate was compared with that of salmeterol/fluticasone propionate in patients with stable, moderate-to-severe chronic obstructive pulmonary disease (COPD).

AFFIRM COPD (Aclidinium and Formoterol Findings in Respiratory Medicine COPD) was a 24-week, double-blind, double-dummy, active-controlled study. Patients were randomised (1:1) to aclidinium/formoterol 400/12 µg twice-daily via Genuair/Pressair or salmeterol/fluticasone 50/500 µg twice-daily via Accuhaler. The primary end-point was peak forced expiratory volume in 1 s (FEV₁) at week 24. Other end-points included Transition Dyspnoea Index (TDI) focal score at week 24, TDI and St George’s Respiratory Questionnaire (SGRQ) responders, COPD Assessment Test and SGRQ scores, assessment of COPD symptoms and exacerbations, use of reliever medication, and device preference. Adverse events were monitored throughout.

In total, 933 patients were eligible (mean age 63.4 years, 65.1% male). Aclidinium/formoterol was superior to salmeterol/fluticasone in peak FEV₁ and noninferior in TDI. Health status and reduction in exacerbation risk were similar in both groups. While both treatments were well tolerated, pneumonia occurred less frequently with aclidinium/formoterol than salmeterol/fluticasone.

In stable COPD, aclidinium/formoterol significantly improved bronchodilation versus salmeterol/fluticasone, with equivalent benefits in symptom control and reduction in exacerbation risk. Both treatments were well tolerated and treatment-related adverse events were less common with aclidinium/formoterol.
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