Tiotropium and olodaterol fixed-dose combination *versus* mono-components in COPD (GOLD 2–4)

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Abstract

Efficacy and safety of tiotropium+olodaterol fixed-dose combination (FDC) compared with the mono-components was evaluated in patients with moderate to very severe chronic obstructive pulmonary disease (COPD) in two replicate, randomised, double-blind, parallel-group, multicentre, phase III trials.

Patients received tiotropium+olodaterol FDC 2.5/5 μg or 5/5 μg, tiotropium 2.5 μg or 5 μg, or olodaterol 5 μg delivered once-daily *via* Respimat inhaler over 52 weeks. Primary end points were forced expiratory volume in 1 s (FEV1) area under the curve from 0 to 3 h (AUC0–3) response, trough FEV1 response and St George's Respiratory Questionnaire (SGRQ) total score at 24 weeks.

In total, 5162 patients (2624 in Study 1237.5 and 2538 in Study 1237.6) received treatment. Both FDCs significantly improved FEV1 AUC0–3 and trough FEV1 response *versus* the mono-components in both studies. Statistically significant improvements in SGRQ total score *versus* the mono-components were only seen for tiotropium+olodaterol FDC 5/5 μg. Incidence of adverse events was comparable between the FDCs and the mono-components.

These studies demonstrated significant improvements in lung function and health-related quality of life with once-daily tiotropium+olodaterol FDC *versus* mono-components over 1 year in patients with moderate to very severe COPD.

Bibliografie aditionala

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