Clinical and Translational Allergy

ORAL PRESENTATION Open Access

O05 - Once-daily tiotropium in adolescents with symptomatic asthma despite inhaled corticosteroid treatment: a dose-ranging study

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From 3rd Pediatric Allergy and Asthma Meeting (PAAM)
Athens, Greece. 17-19 October 2013

Background

Once-daily tiotropium is an effective and safe add-on bronchodilator for asthmatic adults who remain symptomatic despite inhaled corticosteroid (ICS) treatment in accordance with current international guidelines. Despite the wide range of available therapy options, many adolescents with asthma have disease that is sub-optimally controlled.

Methods

This randomised, placebo-controlled, double-blind, incomplete crossover study (NCT01122680) evaluated the efficacy and safety of 5, 2.5 and 1.25 μg once-daily (evening) tiotropium (via Respimat® Soft Mist™ Inhaler) versus placebo in three 4-week treatment periods in adolescents (aged 12-17 years) with symptomatic asthma despite medium-dose ICS. The primary efficacy end point was change in peak forced expiratory volume in 1 second within 3 hours post-dose (peak $FEV_{1(0\text{-}3h)}$) assessed as a response (difference from baseline). Secondary end points included trough FEV_1, FEV_1 area under the curve $(AUC)_{(0\text{-}3h)}$, peak expiratory flow ($PEF_{am/pm}$) responses and Asthma Control Questionnaire (ACQ) score.

Results

Of 139 enrolled patients, 105 were randomised to receive one of four treatment sequences. Peak $FEV_{1(0\text{-}3h)}$ response was statistically significantly greater with 5 μg tiotropium than placebo (difference from placebo: 113 ±39 (SE) mL; p=0.0043). Trough FEV_1 and FEV_1 $AUC_{(0\text{-}3h)}$ responses with 5 μg tiotropium were also significantly higher versus placebo (p<0.0001 and p=0.0001, respectively). A superior PEF_{am} and PEF_{pm} response was observed with 5 μg tiotropium over placebo. Although ACQ scores improved from baseline (2.091) with tiotropium (5 μg, 1.287; 2.5 μg, 1.366; 1.25 μg, 1.189), they also improved with placebo (1.371), which may be due to the short duration of this study. Safety profile was balanced across treatment groups, with the majority of adverse events being mild to moderate in severity and no dose-dependency observed.

Conclusion

This first study of tiotropium as add-on to ICS in adolescents with symptomatic asthma demonstrates that 5 μg tiotropium is an effective and well-tolerated dose.

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Published: 28 February 2014

doi:10.1186/2045-7022-4-S1-O5
Cite this article as: Vogelberg *et al.*: O05 - Once-daily tiotropium in adolescents with symptomatic asthma despite inhaled corticosteroid treatment: a dose-ranging study. *Clinical and Translational Allergy* 2014 **4**(Suppl 1):O5.

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