primary studies - published RCT

Testing Two Different Doses of Tiotropium Respimat(R) in Cystic Fibrosis: Phase 2 Randomized Trial Results.

Code: PM25188297 **Year:** 2014 **Date:** 2014 **Author:** Bradley JM

Study design (if review, criteria of inclusion for studies)

Phase 2, randomized, double-blind, placebo-controlled parallel-group

Participants

510 subjects with cystic fibrosis aged 5-69 years with pre-bronchodilator forced expiratory volume in 1 second (FEV1) >/=25% predicted.

Interventions

2.5 and 5 microg once-daily Tiotropium (a long-acting anticholinergic bronchodilator) delivered via the Respimat Soft Mist Inhaler vs. placebo.

Outcome measures

Co-primary efficacy end points were change from baseline in percent-predicted FEV1 area under the curve from 0 to 4 hours (FEV1 AUC0-4h), and trough FEV1 at the end of week 12.

Main results

Both doses of tiotropium resulted in significant improvement compared with placebo in the co-primary efficacy end points at the end of week 12 (change from baseline in percent-predicted FEV1 AUC0-4h: 2.5 microg: 2.94%, 95% confidence interval 1.19-4.70, p = 0.001; 5 microg: 3.39%, 95% confidence interval 1.67-5.12, p = 0.0001; in percent-predicted trough FEV1ratio2.5 microg: 2.24%, p = 0.2; 5 microg: 2.22%, p = 0.02). There was a greater benefit with tiotropium 5 vs. 2.5 microg. No treatment-related adverse events or unexpected safety findings were observed in patients taking tiotropium.

Authors' conclusions

Tiotropium significantly improved lung function in people with cystic fibrosis. The improvement was greater with the higher dose than the lower dose, with no difference in adverse events.

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See also

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Keywords

Adult; Aged; Bronchodilator Agents; Child; pharmacological_intervention; placebo; tiotropium; Low-Dose; Anticholinergic Agents; Respiratory System Agents; nebuliser; non pharmacological intervention - devices OR physiotherapy;