primary studies - published RCT

A multi-center controlled trial of growth hormone treatment in children with cystic fibrosis.

Code: PM21905270 **Year:** 2012 **Date:** 2015 **Author:** Stalvey MS

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

phase 3 randomized, double-blind, placebo-controlled trial

Participants

patients with CF (N=463)

Interventions

Tiotropium Respimat 5mug once daily

Outcome measures

Co-primary efficacy endpoints: percent-predicted forced expiratory volume in 1s (FEV1) area under the curve from 0-4h (AUC0-4h); percent-predicted FEV1 . Adverse events

Main results

Co-primary efficacy endpoints showed no statistical difference between tiotropium and placebo: percent-predicted forced expiratory volume in 1s (FEV1) area under the curve from 0-4h (AUC0-4h) (95% CI): 1.64% (0.27,3.55; p=0.092); percent-predicted trough FEV1 (95% CI) 1.40% (0.50,3.30; p=0.15). Adverse events were similar between groups. Pooled phase 2/3 trial results showed a treatment difference in favor of tiotropium: percent-predicted FEV1 AUC0-4h (95% CI): 2.62% (1.34,3.90).

Authors' conclusions

Tiotropium was well tolerated in patients with CF; lung function improvements compared with placebo were not statistically significant in the phase 3 trial.

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See also

Pediatr Pulmonol. 2012 Mar;47(3):252-63. doi: 10.1002/ppul.21546. Epub 2011 Sep 8.

Keywords

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