

primary studies - published RCT

A pilot study to compare tobramycin 80 mg injectable preparation with 300 mg solution for inhalation in cystic fibrosis patients.

Code: PM18716688

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

multicentre, double-blind, randomised controlled clinical trial

Participants

cystic fibrosis patients on maintenance treatment with 2.5 mL dornase alfa once daily

Interventions

patients on maintenance treatment with 2.5 mL dornase alfa once daily were switched to a smart nebuliser and randomised to small airway deposition (n = 24) or large airway deposition (n = 25) for 4 weeks.

Outcome measures

The primary outcome parameter was forced expiratory flow at 75% of forced vital capacity (FEF(75%)).

Main results

FEF(75%) increased significantly by 0.7 sd (5.2% predicted) in the large airways group and 1.2 sd (8.8% pred) in the small airways group. Intention-to-treat analysis did not show a significant difference in treatment effect between groups. Per-protocol analysis, excluding patients not completing the trial or with adherence

Authors' conclusions

Improved delivery of dornase alfa using a smart nebuliser that aids patients in correct inhalation technique resulted in significant improvement of FEF(75%) in children with stable cystic fibrosis. Adherent children showed a larger treatment response for small airway deposition.

See also

Can Respir J. 2008 Jul-Aug;15(5):259-62.

Keywords

Deoxyribonuclease; Airway clearance drugs -expectorants- mucolytic- mucociliary-; pharmacological_intervention; Respiratory System Agents; non pharmacological intervention - devices OR physiotherapy; Inhalation OR nebulised; nebuliser; Dornase alpha; Pulmozyme;