primary studies - published RCT

Sequential ciprofloxacin therapy in pediatric cystic fibrosis: comparative study vs. ceftazidime/tobramycin in the treatment of acute pulmonary exacerbations. The Cystic Fibrosis Study Group.

Code: PM9002118 **Year:** 1997 **Date:** 2002 **Author:** Church DA

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

randomised, double-blind, placebo-controlled, dose-escalation and safety study

Participants

19 adults with CF (homozygous deltaF508)

Interventions

Three dose levels (20, 30, or 40 g divided t.i.d.) of drug or placebo were given for 1 week.

Outcome measures

Serial measurements of chloride transport by nasal potential difference (NPD) testing and metabolic safety testing were performed.

Main results

A maximum tolerated dose of 20 g was defined based on minimal adverse reactions, the safety profile, and a statistically significant induction of chloride transport that was maximal by day 3.

Authors' conclusions

This short-term phase I/II study demonstrates proof of principle that modulation of deltaF508 CFTR biosynthesis and trafficking is a viable therapeutic approach for cystic fibrosis.

http://dx.doi.org/10.1097/00006454-199701000-00031

See also

Pediatr Infect Dis J. 1997 Jan;16(1):97-105; discussion 123-6.

Keywords

4-phenylbutyrate; Adult; CFTR Modulators; pharmacological_intervention;