primary studies - published RCT

Safety and efficacy of recombinant alpha(1)-antitrypsin therapy in cystic fibrosis.

Code: PM16372352 **Year:** 2006 **Date:** 2010 **Author:** Martin SL

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

open-label randomised multicentre study

Participants

patients with CF (aged > or = 6 months) with early P aeruginosa infection

Interventions

patients were treated for 28 days with TIS twice daily administered by the PARI LC PLUS (PARI GmbH, Starnberg, Germany) jet nebuliser. After 28 days, patients were randomised 1:1 to either stop TIS (n=45) or to receive a further 28 days of TIS (n=43).

Outcome measures

The primary endpoint was the median time to recurrence of P aeruginosa (any strain). Secondary endpoints included the proportion of patients free of P aeruginosa infection 1 month after cessation of therapy and safety assessments.

Main results

The median time to recurrence of P aeruginosa (any strain) was similar between the two groups. In total, 93% and 92% of the patients were free of P aeruginosa infection 1 month after the end of treatment and 66% and 69% remained free at the final visit in the 28-day and 56-day groups, respectively. TIS was well tolerated.

Authors' conclusions

Treatment with TIS for 28 days is an effective and well tolerated therapy for early P aeruginosa infection in patients with CF.

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See also

Pediatr Pulmonol. 2006 Feb;41(2):177-83.

Keywords

Adolescent; Adult; Anti-Bacterial Agents; Bacterial Infections; Child; Drug Administration Schedule; Infant; Infection; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; Aminoglycosides; Inhalation OR nebulised;