

primary studies - published RCT

Two years experience with recombinant human DNase I in the treatment of pulmonary disease in cystic fibrosis.

Code: PM7480980

Year: 1995 Date: 1999

Author: Shah PL

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

Random allocation. Double blinded. Placebo control. Parallel groups.

Participants

520 participants (54% male). Age from six years, 54% 18 years or older. All infected with *P. aeruginosa*. Baseline FEV1 25-75% predicted. Criteria for CF were CFF clinical practice guidelines.

Interventions

Tobramycin 300 mg or 0.225 normal saline and 1.25 mg quinine twice daily for three 28-day on-off cycles.

Outcome measures

Lung function (FEV1 and FVC), exacerbations (hospitalisation or IV antibiotics), sputum *P. aeruginosa* colony count, renal toxicity, ototoxicity.

Main results

The patients treated with inhaled tobramycin had an average increase in forced expiratory volume in one second (FEV1) of 10 percent at week 20 as compared with week 0, whereas the patients receiving placebo had a 2 percent decline in FEV1 (P

Authors' conclusions

In a 24-week study of patients with cystic fibrosis, intermittent administration of inhaled tobramycin was well tolerated and improved pulmonary function, decreased the density of *P. aeruginosa* in sputum, and decreased the risk of hospitalization.

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See also

Respiratory medicine YR: 1995 VL: 89 NO: 7

Keywords

Adolescent; Adult; Anti-Bacterial Agents; Bacterial Infections; Child; Hospitalization; Hospital care; Infection; Inhalation OR nebulised; Intermittent; Intravenous; nebuliser; non pharmacological intervention - devices OR physiotherapy; pharmacological_intervention; *Pseudomonas aeruginosa*; *Pseudomonas*; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; Aminoglycosides;