primary studies - published RCT

A formulation of aerosolized tobramycin (Bramitob) in the treatment of patients with cystic fibrosis and Pseudomonas aeruginosa infection: a double-blind, placebo-controlled, multicenter study.

Code: PM17536872 **Year:** 2007 **Date:** 2007 **Author:** Chuchalin A

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

Multicentre (21 sites across Hungary, Poland and Russia) parallel study. Randomised, placebo-controlled, double-blind study. A 2:1 (tobramycin: placebo) allocation used.

Participants

Diagnosis of CF + P. aeruginosa. 247 randomised; 245 included in ITT population (135 males, 110 females)

Interventions

Used a Pari LC Plus jet nebuliser and Pari Turbo Boy air compressor. Tobramycin 300 mg (Bramitob®) or placebo (saline solution with quinine hydrochloride solution) for 24 weeks (4 weeks 'on treatment' followed by 4 weeks 'off treatment').

Outcome measures

FEV1, FVC, FEF25-75, sputum (P. aeruginosa density, tobramycin susceptibility), other pathogens, pulmonary exacerbations, use of parenteral anti-pseudomonal antibiotics, number of hospitalisations, loss of school/work days, audiometric test, renal function

Main results

A total of 247 patients were randomized in the study. At endpoint time assessment (week 20), FEV(1) was significantly increased in the tobramycin group and the adjusted mean difference between groups (intention-to-treat population) was statistically significant (p

Authors' conclusions

Long-term, intermittent administration of this aerosolized tobramycin formulation (300mg/4mL) in CF patients with P. aeruginosa chronic infection significantly improved pulmonary function and microbiologic outcome, decreased hospitalizations, increased nutritional status, and was well tolerated.

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See also

Paediatr Drugs. 2007;9 Suppl 1:21-31.

Keywords

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