primary studies - published RCT

Treatment with tobramycin solution for inhalation reduces hospitalizations in young CF subjects with mild lung disease.

Code: PM15334509 **Year:** 2004 **Date:** 2004 **Author:** Murphy TD

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

Open label. Parallel group. Stratified by age and sex. Randomised.

Participants

2 or more cultures of P. aeruginosa. 184 participants (52% males). Age 6 - 15 years.

Interventions

Tobramycin 300 mg twice daily, alternating 4-weekly cycles for 56 weeks.

Outcome measures

Lung function, hospitalisation, antibiotic use.

Main results

Only 184 of 400 planned subjects were recruited and randomized (93 to the TSI group, and 91 to the control group). Enrollment was ended after 2 years because of difficult recruitment. An interim safety review showed a 2.42-fold risk of respiratory hospitalization for control group subjects (P = 0.020), and the study was terminated. Sixty-three subjects (34.2%) completed the entire study (30 in the TSI group, or 32.3%; and 33 in the control group, or 36.3%). Significantly fewer TSI subjects were hospitalized for worsening of respiratory symptoms (11.0% vs. 25.6%; P = 0.011), and fewer TSI subjects were hospitalized overall (16.5% vs. 27.8%; P = 0.065). Fewer TSI subjects received antibiotics other than the study drug (78.0% vs. 95.6%), and significantly fewer received oral antibiotics (76.9% vs. 91.1%; P = 0.009). No other safety or adverse event differences were observed.

Authors' conclusions

significant reductions in respiratory hospitalizations, concomitant antibiotic use, and a trend towards improvement in percent predicted forced expiratory flow (FEF(25-75)) provide evidence of a clinical benefit of TSI use in young persons with CF and mild lung disease. An effect on lung function decline rate could not be evaluated as planned, due to inadequate enrollment and early study termination.

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See also

Pediatr Pulmonol. 2004 Oct;38(4):314-20.

Keywords

Adolescent; Anti-Bacterial Agents; Child; Hospitalization; Hospital care; Inhalation OR nebulised; pharmacological_intervention; Respiratory Tract Diseases; Tobramycin; Bacterial Infections; Respiratory Tract Infections; Infection; Aminoglycosides;