

primary studies - published RCT

## **Risk of persistent growth impairment after alternate-day prednisone treatment in children with cystic fibrosis Comment in: N Engl J Med 2000 Mar 23;342(12):887-8.**

**Code:** PM10727589

**Year:** 2000 **Date:** 2004

**Author:** Lai HC

### **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.

<http://www.mrw.interscience.wiley.com/cochrane/clcentral/articles/418/CN-00291418/frame.html>

### **See also**

N Engl J Med. 2000 Mar 23;342(12):851-9.

### **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;