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primary studies - published RCT

## Treatment of early *Pseudomonas aeruginosa* infection in patients with cystic fibrosis: the ELITE trial.

**Code:** PM19996339

**Year:** 2010 **Date:** 2010

**Author:** Ratjen F

### 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.

<http://dx.doi.org/10.1136/thx.2009.121657>

### See also

Thorax. 2010 Apr;65(4):286-91. Epub 2009 Dec 8.

### 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;