

primary studies - published RCT

## Long-term efficacy and safety of aerosolized tobramycin 300 mg/4 ml in cystic fibrosis.

Code: PM24464974

Year: 2014 Date: 2014

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

Randomized open-label trial

### Participants

CF patients aged  $\geq 6$  years having baseline 1 sec forced expiratory volume (FEV(1)) 40-80% predicted.

### Interventions

Patients were initially randomized in an 8-week open-label trial (core phase) to compare TNS4 (N = 159) and tobramycin 300 mg/5 ml (TNS5, TOBI((R))) (N = 165). A subset of patients continued in a 48-week, single-arm extension receiving TNS4 only.

### Outcome measures

The primary endpoint of the core phase was to demonstrate the non-inferiority of TNS4 compared to TNS5 in terms of absolute change from baseline to week 4 in FEV(1) % predicted. The assessment of long-term safety was the primary purpose of the extension phase. Throughout all phases of the study, microbiological assessments, adverse events, and audiometry findings were also evaluated.

### Main results

In the core phase (N = 321), FEV(1) (% predicted) increased from baseline (absolute change) following a single on-treatment cycle for both TNS4 (7.0%) and TNS5 (7.5%) and the non-inferiority between treatments was met [difference between treatments of -0.5 (95% CI: -2.6; 1.6)]. These improvements were maintained throughout the extension phase (N = 209), ranging throughout the study between 5.1% (95% CI: 3.2; 6.9) and 8.1% (95% CI: 6.8; 9.4) compared to baseline. Pa sputum count reductions ranged between 0.6 (95% CI: 0.2; 0.9) to 2.3 (95% CI: 2.0; 2.6) log<sub>10</sub> CFU/g throughout the 56 weeks. No remarkable safety issues were identified throughout both study phases, with similar percentages of patients reporting adverse events in the two treatment groups during the 8-week core phase [TNS4 (31.4%); TNS5 (28.0%)].

### Authors' conclusions

Overall, TNS4 demonstrated short-term clinical benefits similar to TNS5 which were maintained during the long-term use of TNS4 and was also associated with a favorable tolerability profile.

<http://dx.doi.org/10.1002/ppul.22989>

### See also

Pediatr Pulmonol. 2014 Nov;49(11):1076-89. doi: 10.1002/ppul.22989. Epub 2014 Jan 24.

### Keywords

Adolescent; Adult; Anti-Bacterial Agents; Bacterial Infections; Child; Infection; Inhalation OR nebulised; nebuliser; non pharmacological intervention - devices OR physiotherapy; pharmacological\_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; Aminoglycosides;