primary studies - published RCT

Comparison of two tobramycin nebuliser solutions: pharmacokinetic, efficacy and safety profiles of T100 and TNS.

Code: PM24836961 **Year:** 2014 **Date:** 2014 **Author:** Sands D

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

Randomized, open-label, multicentre, two-period, crossover study

Participants

58 patients with CF and chronic Pseudomonas aeruginosa (PA) infection

Interventions

two tobramycin nebuliser solutions: T100/eFlow or TNS/PARI LC PLUS.

Outcome measures

The primary objective was to demonstrate the equivalence of both treatments with respect to pharmacokinetics (area under the concentration-time curve and maximum concentration in plasma). Secondary endpoints were tobramycin sputum pharmacokinetics, reduction in PA colony forming units, improvement of lung function, incidence of adverse drug reactions and reduction of inhalation times.

Main results

Tobramycin plasma AUC and Cmax were lower after administration of T100 than after TNS. The study failed to demonstrate systemic bioequivalence of the two treatments. After T100 administration, tobramycin sputum AUC and Cmax achieved higher values than after TNS. Changes in efficacy parameters from baseline were similar. Safety profiles were not different or unexpected. Inhalation time per inhalation was shorter during treatment with T100.

Authors' conclusions

The lower systemic drug burden and the higher local drug deposition together with a comparable efficacy/safety profile and a shorter inhalation time render T100/eFlow an attractive treatment option for CF patients.

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See also

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Keywords

Anti-Bacterial Agents; Pseudomonas aeruginosa; Pseudomonas; Tobramycin; Bacterial Infections; Infection; Inhalation OR nebulised; nebuliser; non pharmacological intervention - devices OR physiotherapy; pharmacological_intervention; Respiratory Tract Diseases; Respiratory Tract Infections; Airway clearance technique; Vibration; Aminoglycosides; oscillating devices; Chest physiotherapy;