

primary studies - published RCT

Comparison of a beta-lactam alone versus beta-lactam and an aminoglycoside for pulmonary exacerbation in cystic fibrosis.

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Author: Smith AL

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

open-label extension phase of a large, placebo-controlled study

Participants

Patients from both treatment arms (n=396)

Interventions

Patients from both treatment arms received up to nine 28-day on, 28-day off cycles of TNS 300 mg by aerosol twice daily (b.i.d.).

Outcome measures

lung function and adverse events

Main results

Mean lung function in patients who had received placebo during the double-blind phase improved during the first three cycles of the open-label treatment. However, lung function in these patients did not recover to the levels seen in those patients who had received TNS throughout the double-blind and open-label phases. In both groups of patients, improvement was maintained during the study. Greater improvements were seen in adolescents compared with older patients. Adverse events were generally uncommon, with a notably lower incidence of fever, anorexia, abdominal pain and vomiting than was observed in the double-blind phase among patients who received placebo, and a generally low incidence of tinnitus.

Authors' conclusions

long-term TNS administration is safe and effective.

[http://dx.doi.org/10.1016/S0022-3476\(99\)70197-6](http://dx.doi.org/10.1016/S0022-3476(99)70197-6)

See also

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Keywords

Adolescent; Adult; Anti-Bacterial Agents; Bacterial Infections; Child; Infection; Inhalation OR nebulised; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; Aminoglycosides;