primary studies - published RCT

Pilot safety study of liposomal prostaglandin (PGE1) in respiratory exacerbations in cystic fibrosis.

Code: PM15463813 **Year:** 2002 **Date:** 2002 **Author:** Taylor CJ

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

Randomised, double-blind, placebo-controlled study

Participants

20 P. aeruginosa colonised CF patients.

Interventions

All received intravenous antibiotics. Subjects were given a rising dose of TLC C-53 (0.15-1.8 microg/kg) by 4 x 1-h infusions.

Outcome measures

Primary outcome measures were sputum IL-6, IL-8 and sputum neutrophil elastase. The rate of decline in lung function was determined at 6 weeks post-therapy as was the interval until the next respiratory exacerbation requiring intravenous antibiotic therapy.

Main results

Analysis of primary and secondary outcome measures failed to show any significant differences between the two groups, although trends favoured the treated group. Decline in lung function over 6 weeks favoured the TLC C-53 group (FEV(1) mean difference 4.3%, 95% CI=-6.8, 15.4%). Time to next exacerbation also favoured the TLC C-53 group with a mean time to exacerbation for TLC C-53 of 26.0 weeks against 11.9 weeks.

Authors' conclusions

A larger multi-centre trial of TLC C-53 as an adjunct to antibiotic therapy in respiratory exacerbations in CF would appear warranted.

http://www.journals.elsevier.com/journal-of-cystic-fibrosis/

See also

J Cyst Fibros. 2002 Jun;1(2):90-3.

Keywords

Adolescent; Alprostadil; Anti-Bacterial Agents; Anti-Inflammatory Agents; Bacterial Infections; Infection; Intravenous; pharmacological_intervention; Phosphatidylcholines; Prostaglandins; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Exacerbation; 4-phenylbutyrate; Gastrointestinal Agents; Anti-Inflammatory Agents - excl Steroids;