*primary studies - published RCT*

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

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### 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;