

primary studies - published RCT

## Randomised controlled trial of inhaled corticosteroids (fluticasone propionate) in cystic fibrosis.

**Code:** PM9301350

**Year:** 1997 **Date:** 2002

**Author:** Balfour-Lynn IM

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

Phase II, double-blind, randomised, placebo-controlled clinical trial

### Participants

23 CF patients

### Interventions

For each patient, a dose of 100,000 replication units of tgAAVCF was administered to one maxillary sinus, while the contralateral maxillary sinus received a placebo treatment, thereby establishing an inpatient control.

### Outcome measures

primary efficacy endpoint (rate of relapse of clinically defined, endoscopically diagnosed recurrent sinusitis); secondary endpoints (sinus transepithelial potential difference [TEPD], histopathology, sinus fluid interleukin [IL]-8 measurements, sinus fluid cytokine IL-10), adverse events, sinus histopathology, serum-neutralizing antibody titer to adeno-associated virus (AAV) capsid protein

### Main results

Neither the primary endpoint, nor several secondary endpoints achieved statistical significance when comparing treated to control sinuses within patients. cytokine IL-10 in sinus fluid, was significantly (p

### Authors' conclusions

this Phase II trial confirms the safety of tgAAVCF but provides little support of its efficacy in the within-patient controlled sinus study. Various potentially confounding factors are discussed.

<http://dx.doi.org/10.1136/adc.77.2.124>

### See also

Arch Dis Child. 1997 Aug;77(2):124-30.

### Keywords

Adolescent; Adult; Bacterial Infections; Gene Transfer Techniques; Infection; Instillation- Drug; Intranasal; non pharmacological intervention - genetic& reprod; pharmacological\_intervention; placebo; Respiratory Tract Diseases; Respiratory Tract Infections; Virus; tgAAVCF;