primary studies - published RCT

Dornase alfa as postoperative therapy in cystic fibrosis sinonasal disease.

Code: PM16365224 **Year:** 2005 **Date:** 2005 **Author:** Cimmino M

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

Prospective, randomized, double-blind tria

Participants

Twenty-nine (11%) of 256 patients with CF who were surgically treated for chronic sinusitis with or without nasal polyps were consecutively enrolled. Five withdrew immediately before randomisation without starting any treatment owing to a prolonged illness after surgery. Twenty-four patients with sinonasal disease (13 girls and 11 boys; mean ± SD age, 10.6 ± 2.7 years; age range, 7-15 years) were randomized.

Interventions

One month after surgery, patients were randomly assigned to receive for 1 year either dornase alfa or placebo.Treatment group (n=12): 4 consecutive 8-week treatment cycles with once-daily 2.5-mg doses of dornase alfa (in 2.5 mL of vehicle; Genentech, San Francisco, Calif) separated by 4-week washout periods. Placebo group (n=12): 4 consecutive 8-week treatment cycles with placebo inhalation (21.9 mg of sodium chloride and 0.38 mg of calcium chloride in 2.5 mL of water for inhalation) (Genentech) separated by 4-week washout periods. Both therapies were iso-osmolar and administered into both nostrils in the morning via a Sidestream nebulizer and Portaneb compressor (Medic-Aid Ltd, West Sussex, England), with a mean daily inhalation time of 11 minutes.

Outcome measures

Primary outcome: assessment of nasal-related symptoms and nasal endoscopic appearance. Secondary outcomes: results of nasal radiologic examination, saccharine clearance test, and FEV1. At each visit, the severity of 6 symptoms was evaluated on a well-established scale: (1) facial pain or pressure, (2) headache, (3) nasal blockage and congestion, (4) nasal discharge, (5) olfactory disturbance, and (6) overall discomfort.

Main results

After surgery, all outcomes were significantly improved for each treatment at 1 month (P

Authors' conclusions

Nasally inhaled dornase alfa can be effective in patients with cystic fibrosis and sinonasal disease who do not respond to conventional therapy after surgical treatment. Further studies should be carried out to determine the long-term effect on sinus disease, recurrence of polyps, and quality of life.

http://dx.doi.org/10.1001/archotol.131.12.1097

See also

Arch Otolaryngol Head Neck Surg. 2005 Dec;131(12):1097-101.

Keywords

Adolescent; Bacterial Infections; Child; Deoxyribonuclease; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Infection; Intranasal; pharmacological_intervention; Recombinant Proteins; Respiratory System Agents; Respiratory Tract Infections; Sinusitis; Inhalation OR nebulised; Sodium Chloride; Respiratory Tract Diseases; Dornase alpha; Pulmozyme;