primary studies - published RCT

Efficacy and tolerability of a new nasal spray formulation containing hyaluronate and tobramycin in cystic fibrosis patients with bacterial rhinosinusitis.

Code: PM24656944 **Year:** 2014 **Date:** 2014 **Author:** Di Cicco M

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

double-blind randomized controlled study

Participants

patients with an established diagnosis of CF and a documented nasal infection with Pseudomonas aeruginosa and/or Staphylococcus aureus [22 males (81%), median age of 15years (range 5-26yrs)]

Interventions

patients were randomized to receive the nasal spray formulation containing hyaluronate and tobramycin (N=14) or hyaluronate alone (N=13) for 14days.

Outcome measures

Efficacy and local tolerability of the treatments were assessed by ear, nose and throat (ENT) examination and related symptoms.

Main results

The formulation containing hyaluronate and tobramycin was more effective than hyaluronate alone in improving the status of the nasal mucosa, in reducing the mucopurulent secretion at the level of the osteomeatal complex and in improving ENT symptoms (hyposmia/anosmia and headache/facial pain). The treatment was well tolerated without relevant side effects.

Authors' conclusions

The present study suggests that the combination therapy with hyaluronate plus tobramycin was more effective than hyaluronate alone in the treatment of bacterial rhinosinusitis in CF. Trial registration number: EudraCT 2007-003628-39.

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See also

J Cyst Fibros. 2014 Mar 18. pii: S1569-1993(14)00046-0. doi: 10.1016/j.jcf.2014.02.006.

Keywords

Adolescent; Child; Adult; hyaluronic acid; hydration; Inhalation OR nebulised; pharmacological_intervention; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Respiratory System Agents; nebuliser; non pharmacological intervention - devices OR physiotherapy; Sinusitis; Respiratory Tract Infections; Respiratory Tract Diseases; Infection; Bacterial Infections; Anti-Bacterial Agents; Pseudomonas aeruginosa; Pseudomonas; Tobramycin; Staphylococcus aureus; Aminoglycosides; Intranasal;