

primary studies - published RCT

Sino nasal inhalation of isotonic versus hypertonic saline (6.0%) in CF patients with chronic rhinosinusitis - Results of a multicenter, prospective, randomized, double-blind, controlled trial.

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

RCT, crossover design

Participants

Sixty nine CF patients with chronic rhinosinusitis in eleven German CF centers

Interventions

Patients were randomized to receive sinonasal vibrating inhalation of either NaCl 6.0% or NaCl 0.9% for 28days. After 28days of wash-out, patients crossed over to the alternative treatment.

Outcome measures

The primary outcome parameter was symptom score in the disease-specific quality of life Sino-Nasal Outcome Test-20 (SNOT-20). Additionally, pulmonary function was assessed, as well as rhinomanometry and inflammatory markers in nasal lavage (neutrophil elastase, interleukin (IL)-1beta, IL-6, and IL-8) in a subgroup.

Main results

Both therapeutic arms were well tolerated and showed slight improvements in SNOT-20 total scores (NaCl 6.0%: -3.1+/-6.5 points, NaCl 0.9%: -5.1+/-8.3 points, ns). In both treatment groups, changes of inflammatory parameters in nasal lavage from day 1 to day 29 were not significant. Authors suppose that the irritating properties of NaCl 6.0% reduced the suitability of the SNOT-20 scores as an outcome parameter. Alternative primary outcome parameters such as MR-imaging or the quantity of sinonasal secretions mobilized with both saline concentrations were, however, not feasible.

Authors' conclusions

Sinonasal inhalation with NaCl 6.0% did not lead to superior results vs. NaCl 0.9%, whereas dornase alfa had been significantly more effective than NaCl 0.9%.

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See also

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Keywords

hydration; Hypertonic Solutions; Inhalation OR nebulised; pharmacological_intervention; Airway clearance drugs -expectorantsmucolytic- mucociliary-; Respiratory System Agents; Bacterial Infections; Isotonic Solutions; Respiratory Tract Infections; Sinusitis; Respiratory Tract Diseases;