primary studies - published RCT

Hyaluronic Acid Improves the Tolerability of Hypertonic Saline in the Chronic Treatment of Cystic Fibrosis Patients: A Multicenter, Randomized, Controlled Clinical Trial.

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

Randomized, double-blind, controlled clinical trial. Patients were randomized into randomly permuted blocks. Patients, all caregivers, and the statistician who conducted the analysis (different from the one who generated the random list) were blinded to group assignment.

Participants

Four cystic fibrosis (CF) centers in Italy. Participants were CF patients at least 8 years old, in clinically stable conditions, with forced expiratory volume in 1 sec (FEV1) at least 50% predicted. Forty patients were recruited.

Interventions

Patients were randomized to receive either hypertonic saline (HS) or HS plus hyaluronic acid (HA) (5 mL to be inhaled over 15 min, twice daily for 28 days). The first and last doses were administered in hospital. In between, patients were treated at home.

Outcome measures

Primary endpoints were cough, throat irritation, salty taste, and overall acceptability, as assessed by each patient on a semiquantitative scale on a diary card. Secondary endpoint was FEV1 change at the end of treatment.

Main results

Severity of cough, throat irritation, and saltiness were more severe in patients treated with HS alone, both after the first inhalation and over the entire treatment period. Overall pleasantness was rated higher by patients treated with the combination product. All differences were highly significant. There were no changes in FEV1 between the first and last administrations. Five patients did not complete the study. Four patients (two from each group) withdrew because of cough or throat irritation. One more patient from the HS group withdrew because of a respiratory exacerbation at week 3.

Authors' conclusions

HS is currently a cornerstone in the treatment of CF patients. The addition of HA to HS reduces the prevalence and severity of cough, throat irritation, and saltiness and may improve compliance in patients who previously did not tolerate HS well on its own. Longer-term studies could further assess the benefit of chronic treatment.

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See also

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Keywords

Adolescent; Child; hyaluronic acid; hydration; Hypertonic Solutions; Inhalation OR nebulised; pharmacological_intervention; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Respiratory System Agents; nebuliser; non pharmacological intervention - devices OR physiotherapy;