primary studies - published RCT

Dose-finding and 24-h monitoring for efficacy and safety of aerosolized Nacystelyn in cystic fibrosis.

Code: PM11866009 **Year:** 2002 **Date:** 2002 **Author:** App EM

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

RCT

Participants

study 1: 10 CF patients; study 2: 12 CF patients

Interventions

Study 1: on five consecutive scheduled treatment days, patients inhaled either from two (4 mg) to eight puffs (16 mg) of a single dose of NAL from the range, or 12 puffs of active NAL (24 mg) versus 12 puffs of placebo. Study 2: on different scheduled treatment days, 7 days apart, patients inhaled a single dose of 12 puffs of active NAL (24 mg) or 12 puffs of placebo drug

Outcome measures

Study 1: pulmonary function, adeverse events, sputum viscoelasticity, sputum chloride and sodium concentrations. Study 2: sputum viscoelasticity, adverse events

Main results

Study 1: Pulmonary function data were unaffected and clinically-adverse effects were limited to wheezing in some patients that inhaled 12 puffs of either placebo or active drug. Subsequent rheological analysis of their sputum showed a dose-dependent decrease in sputum viscoelasticity, accompanied by a decrease in sputum solids content and an increase in chloride and sodium concentrations. Study 2: Mucus rigidity decreased following NAL inhalation, with the maximum effect observed at 4 h; the 1-, 2- and 4-h NAL rheology results were significantly different from placebo. No adverse effects were observed. The drug was well tolerated in both studies.

Authors' conclusions

Sputum results were predictive of improved clearability by ciliary and cough transport mechanisms.

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See also

Eur Respir J. 2002 Feb;19(2):294-302.

Keywords

Acetylcysteine; Adolescent; Adult; Artificial Ventilation; Inhalation OR nebulised; Nacystelyn; nebuliser; non pharmacological intervention - devices OR physiotherapy; pharmacological_intervention; Supplementation; Ventilators; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Drug Administration Schedule; thiols; Antioxidants; Respiratory System Agents; N Acetylcysteine;