primary studies - published RCT

A four week trial of hypertonic saline in children with mild cystic fibrosis lung disease: Effect on mucociliary clearance and clinical outcomes.

Code: PM32669217 **Year:** 2020 **Date:** 2020 **Author:** Donaldson SH

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

Randomized, placebo controlled, double blind study

Participants

Children with CF who had minimal lung disease

Interventions

Hypertonic saline 6% versus 0.12% sodium chloride, delivered three-times daily with an eFlow nebulizer for 4 weeks.

Outcome measures

Mucociliary clearance (MCC) was measured using gamma scintigraphy at baseline, 2-hours after the first study treatment, and ~12-hours after the final dose (at day 28). Spirometry, respiratory symptoms (CFQ-R), and safety were also assessed.

Main results

Study treatments were generally well tolerated and safe. HS (6% sodium chloride) resulted in a significant, sustained improvement from baseline in whole lung clearance after 4 weeks of therapy ($p = 0.014$), despite absence of a prolonged single-dose effect after the initial dose. This sustained change (12 hrs after prior dose) was significantly greater when compared to placebo (0.12% sodium chloride) treatment ($p = 0.016$). Improvements in spirometry with HS did not reach statistical significance but correlated with MCC changes.

Authors' conclusions

The observed sustained improvement in MCC with HS suggests that this treatment may yield health benefits, even in relatively mildly affected children with CF. Highlighting this physiologic finding is important due to the lack of meaningful, validated endpoints in this population.

http://dx.doi.org/10.1016/j.jcf.2020.07.009

See also

J Cyst Fibros. 2020 Jul 12. pii: S1569-1993(20)30801-8. doi: 10.1016/j.jcf.2020.07.009.

Keywords

Inhalation OR nebulised; nebuliser; non pharmacological intervention - devices OR physiotherapy; hydration; Hypertonic Solutions; pharmacological_intervention; Respiratory System Agents;