primary studies - published RCT

Preventative Inhalation of Hypertonic Saline in Infants with Cystic Fibrosis (PRESIS): A Randomized, Double-Blind, Controlled Study.

Code: PM30409023 **Year:** 2018 **Date:** 2018 **Author:** Stahl M

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

randomized, double-blind, controlled trial

Participants

42 infants with CF less than 4 months of age

Interventions

Inhalation with hypertonic saline (HS) compared to isotonic saline (IS) patients were randomized across 5 sites to twice daily inhalation of 6% HS (n=21) or 0.9% IS (n=21) for 52 weeks.

Outcome measures

LCI, MRI, adverse events, weight gain, pulmonary exacerbations.

Main results

Inhalation of HS and IS was generally well tolerated by CF infants and the number of adverse events did not differ between groups (P=0.49). The change in LCI from baseline to week 52 was larger in CF infants treated with HS (-0.6) compared to IS (-0.1, P

Authors' conclusions

Preventive inhalation with HS initiated in the first months of life was safe and well tolerated, and resulted in improvements in LCI and weight gain in infants with CF. Our results support feasibility of LCI as endpoint in randomized controlled trials in infants with CF.

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See also

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Keywords

Child; hydration; Hypertonic Solutions; pharmacological_intervention; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Respiratory System Agents;