primary studies - published RCT

The effect of inhaled hypertonic saline on lung structure in children aged 3-6 years with cystic fibrosis (SHIP-CT): a multicentre, randomised, double-blind, controlled trial.

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

Multicentre, randomised, double-blind, controlled study at 23 cystic fibrosis centres

Participants

Children aged 3-6 years who were able to cooperate with chest CT imaging and comply with daily nebuliser treatment.

Interventions

Children aged 3-6 years with cystic fibrosis

Outcome measures

Participants were randomly assigned 1:1 to receive inhaled 2 puffs of 100 Î¼g salbutamol followed by 4mL of either 7% hypertonic saline or 0Â·9% isotonic saline twice per day for 48 weeks. Randomisation was stratified by age in North America and Australia, and by age and country in Europe. Chest CTs were obtained at baseline and 48 weeks and scored using the Perth-Rotterdam Annotated Grid Morphometric Analysis for Cystic Fibrosis (PRAGMA-CF) method.

Main results

Between May 24, 2016, and Dec 18, 2019, 134 children were assessed for inclusion. 18 patients were excluded (nine had incomplete or unsuccessful chest CT at enrolment visit, two could not comply with CT training, two had acute respiratory infection, two withdrew consent, two for reasons unknown, and one was already on hypertonic saline). 116 participants were enrolled and randomly assigned to hypertonic saline (n=56) or isotonic saline (n=60). 12 patients dropped out of the study (seven in the hypertonic saline group and five in the isotonic saline group). Mean PRAGMA-CF %Disease at 48 weeks was 0·88% (95% CI 0·60-1·16) in the hypertonic saline group and 1·55% (1·25-1·84) in the isotonic saline group (mean difference 0·67%, 95% CI 0·26-1·08; p=0·0092) based on a linear regression model adjusted for baseline %Disease values and baseline age. Most adverse events in both groups were rated as mild, and the most common adverse event in both groups was cough.

Authors' conclusions

Inhaled hypertonic saline for 48 weeks had a positive effect on structural lung changes in children aged 3-6 years with cystic fibrosis relative to isotonic saline. This is the first demonstration of an intervention that alters structural lung disease in children aged 3-6 years with cystic fibrosis.

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See also

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Keywords

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