**Normal saline for children with bronchiolitis**

- a Randomized Controlled Non-inferiority Trial

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**Abstract:**

*Background*Bronchiolitis is one of the most common reasons for hospital admissions in early childhood. As supportive treatment, some treatment guidelines suggest using nasal irrigation of normal saline (NS) to facilitate clearance of mucus from the airways. In addition, most pediatric departments in Denmark use nebulized NS for the same purpose, which can mainly be administered as inpatient care. However, no studies have ever directly tested the effect of saline in children with bronchiolitis.

*Methods and analysis*The study is an investigator-initiated, multicenter, open label, randomized, controlled non-inferiority trial, and will be performed at six pediatric departments in Eastern Denmark. We plan to include 300 children aged 0-12 months admitted to hospital with bronchiolitis. Participating children are randomized 1:1:1 to either nebulized NS, nasal irrigation with NS, or no saline therapy. All other treatment will be given according to standard guidelines.

The primary outcome is duration of hospitalization, analyzed according to intention-to-treat analysis using linear regression and Cox regression analysis. By including at least 249 children, we can prove non-inferiority with a limit of 12 hours admission, alpha 2.5% and a power of 80%. Secondary outcomes are need for respiratory support with nasal continuous positive airway pressure or high-flow oxygen therapy, and requirement of fluid supplements (either by nasogastric tube or intravenous).

*Perspectives*

This study may inform current practice for supportive treatment of children with bronchiolitis. First, if NS is found to be helpful, it may be implemented into global guidelines. If no effect of NS is found, we can stop spending resources on an ineffective treatment. Second, if NS is effective, but nasal irrigation is non-inferior to nebulization, it may reduce the workload of nurses, and possibly duration of hospitalization, because the treatment can be delivered by the parents at home.

*Trial Registration:* The study has been registered at ClinicalTrials.gov (NCT05902702)