Effect of inhaled hypertonic saline solution to treat infants hospitalizid with viral bronchiolitis.

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We hypothesize that inhalation of hypertonic saline will reduce the hospital stay.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27764

Bron
NTR

Verkorte titel
N/A

Aandoening

viral bronchiolitis
hypertonic saline solution
infants
hypertoon zout
zuigelingen
RSV

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- The primary end point is the time to discharge, including duration of the treatment following a possible transfer to a paediatric intensive care unit. Discharge is defined as the time from which no additional oxygen therapy is required (oxygen saturation in rest in room air > 95%) and / or no need for intravenous fluids or gastric tube feeding for at least 12 hours. These criteria apply even in cases where actual discharge from hospital is delayed for logistical or social reasons.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Acute viral bronchiolitis is usually caused by the Respiratory Syncytial Virus (RSV). RSV is one of the most common causes of serious airway infections in young infants. At this time there is only symptomatic, supportive treatment possible. None of these treatments is evidence-based. Hypertonic saline is thought to have possible positive effects on bronchiolitis. Recent literature from Israel shows a reduction in hospital stay by 25% after inhalation of 3% hypertonic saline solution as an additional treatment for bronchiolitis, however in a small number of patients.

We hypothesize that inhalation of hypertonic saline will reduce the hospital stay. We want to answer the question which effect different concentrations of hypertonic saline solution have on hospital stay in infants with viral bronchiolitis.

Objective:
The primary objective is the duration of admission. Secondary objectives are the necessity for transfer to a Pediatric Intensive Care Unit (PICU) if there is the need for mechanical ventilation, the duration of need for supplemental oxygen and the necessity for supportive treatment, furthermore the influence of the different kind of viruses on the course of disease and reaction to the treatment.

Study design:
Multicenter randomised double-blind placebo-controlled intervention trial.

Study population:

Children younger than two years with virale bronchiolitis admitted to hospital.

Intervention:
The trial treatment consists of nebulization with hypertonic saline with either a 2.93% for the first intervention group or a 5.85% concentration for the second intervention group. The control group will receive nebulised physiologic saline solution. All nebulizations will be done three times daily with 2.5mg Salbutamol added.

Main study parameters / endpoints:
The primary end point is the time to discharge. The main study parameter is to achieve a 25% reduction in hospital stay.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: All infants will receive a single trial inhalation with Salbutamol 2.5 mg and nasal lavage will be taken to determine the causing agent, as is usual in diagnostic and treatment of bronchiolitis. Before and after each nebulization - which is done three times a day - the heart rate, oxygen saturation, respiratory rate, temperature and Wang score will be recorded. Participating infants nebulize relatively low concentrations, 2.93% and 5.85%, of hypertonic saline to avoid the negative side effects and the saline solution will always be nebulized in combination with salbutamol to prevent bronchoconstriction. There are no known side effects resulting from nebulized 2.93% or 5.85% hypertonic or 0.9% normotonic saline. The fact that bronchiolitis mostly is seen in infants below 2 years of age and that there isn’t any evidence based treatment available warrants studying the effect of hypertonic saline in this patientgroup. The fact that bronchiolitis is an infection of the lower respiratory tract and hypertonic saline has a local effect suggests that nebulization as with hypertonic saline will show the best improvement.

Doel van het onderzoek

We hypothesize that inhalation of hypertonic saline will reduce the hospital stay.

Onderzoeksopzet

The range of 1 bronchiolitis season, about 6 months.

Infants will be studied during hospitalization.

Onderzoeksproduct en/of interventie

All children included in the study will have a nasopharyngeal lavage. Therefor 1 cc of NaCl 0,9% is injected by a 2cc-syringe in each side of the nose. Then the nasopharyngeal secretion is sucked out with the Muco-Safe (Muco-Safe with filter, Ch10, 40cm, Unomedical A / S, Denemarken) from both sides of the nose, followed by sucking 2 cc of saline to be sure that al the secretion will be within the Muco-Safe-reservoir. The reservoir will be closed hermetically.

Following this all children will be nebulized three times daily with either hypertonic or physiological saline.

Trial medication will be administered through a firmly applied facemask with a constant oxygen supply of 6 - 8 L/min from a wall outlet. The same state-of-the-art nebulising equipment (Sidestream; Romedic BV; Meersen, the Netherlands) will be used in all patients.

Before and after nebulisation the heart rate, transcutaneous oxygen saturation, respiratory rate, temperature and Wang score will be recorded.21 With this score the respiratory rate, presence of wheezing and retractions will be scored on a four-point scale (Supplement 1). A symptom score will be calculated by adding up these three separate items, yielding a score ranging from 0 till 9.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Infants younger than 24 months admitted with a viral bronchiolitis (prolonged and/or wheezing exspiration, tachypnoe and dyspnoe), a Wang-score of two or more and without a positive reaction on Salbutamol inhalation are included, after informed parental consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Haemodynamically important congenital cardiac disease.

2. Chronic pre-existent respiratory disease, T-cell immunodeficienty and admission of the patient with a viral bronchiolitis not due to clinical reasons, for instance social problems.

3. Infants who are treated with systemic corticosteroids will also be excluded from the study.

4. Infants suspected to have underlying asthma and/or allergy. This includes infants with eczema or food-allergy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2009
Aantal proefpersonen:	161
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1433
NTR-old	NTR1494
Ander register	NL21828-068.08 : 21828
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A