Mucus in paediatric mechanical ventilation.

Gepubliceerd: 10-08-2009 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24021

Bron
NTR

Verkorte titel
N/A

Aandoening

Mechanical ventilation, sputum productgion

Ondersteuning

Primaire sponsor: N/A
Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To study the differences in changes in EELV between mechanically ventilated children after endotracheal suctioning with prior nebulisation of ipratropriumbromide, prior instillation of

NaCl 0.9% or nothing.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Ipratropiumbromide (Atrovent®) is an ammonium-containing muscarinic antagonist (i.e. an anticholinergic agent) that conceptually may decrease sputum production with resulting increase in lung volume defined by end-expiratory lung volume (EELV) and improved oxygenation. However, its efficacy on these outcomes is unclear that warrants further study to rationalise this supportive treatment.

Objective:

1. To study the differences in changes in EELV between mechanically ventilated children after endotracheal suctioning with prior nebulisation of ipratropriumbromide, prior instillation of NaCl 0.9% or nothing;

2. To study the differences in PaO2/FiO2 and oxygenation index between mechanically ventilated children after endotracheal suctioning with prior nebulisation of ipratropriumbromide, prior instillation of NaCl 0.9% or nothing.

Study design:
The study is designed as a prospective, randomized interventional pilot study in the period September – December 2009.

Study population:
All mechanically ventilated children aged 0 – 18 years old.

Intervention (if applicable):
Patients will be randomized to either nebulisation of ipratropiumbromide (if age less than 4 years 125 micrograms, if age > 4 years then 250 micrograms) four times a day, endotracheal installation of sodium chloride (NaCl 0.9%) 2 – 4 ml or to control group (no intervention at all).

Main study parameters/endpoints:
Primary endpoint includes the difference in changes in EELV measured with EIT. Secondary endpoints include the difference in oxygenation defined by PaO2 ratio and the oxygenation index (OI).

Doel van het onderzoek

We hypothesize that nebulisation of ipratropiumbromide results in decreased production of

sputum resulting in a better lung aeration (defined by an increase in EELV) and improved oxygenation (as defined by the PaO2/FiO2 ratio and the oxygenation index) in a heterogeneous group of mechanically ventilated critically ill children.

Onderzoeksopzet

The study periods lasts 24 hours after inclusion, incorporating 4 time points at which measurements are made.

Onderzoeksproduct en/of interventie

Patients will be randomized to either nebulisation of ipratropiumbromide (if age less than 4 years 125 micrograms, if age > 4 years then 250 micrograms) four times a day, endotracheal installation of sodium chloride (NaCl 0.9%) 2 – 4 ml or to control group (no intervention at all).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Children are eligible for inclusion if they meet the following criteria:

1. Pressure-controlled mechanical ventilation for at least 24 hours;

2. Endotracheal tube leakage < 5% (as measured by the mechanical ventilator);

3. Informed consent obtained from parents or legal caretakers.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Mechanical ventilation less than 24 hours or children on high-frequency oscillatory ventilation;

2. Endotracheal tube leakage > 5%;

3. Pre-existing pulmonary abnormalities;

4. Pre-existing congenital heart disease with significant left-to-right shunt.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	10-01-2009

Aantal proefpersonen:	45
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-08-2009
Soort:	Eerste indiening

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	NL1838
NTR-old	NTR1948
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A