Mucus in paediatric mechanical ventilation.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24021

Source
NTR

Brief title
N/A

Health condition

Mechanical ventilation, sputum productgion

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

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 description

Background summary

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).

Study objective

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.

Study design

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

Intervention

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).

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-01-2009
Enrollment:	45
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-08-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1838
NTR-old	NTR1948
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A