The effect of nebulisation of ipratropiumbromide on oxygenation and end-expiratory lung volume in mechanically ventilated children: a pilot study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON32902

Source
ToetsingOnline

Brief title
Mucus in paediatric mechanical ventilation

Condition

- Respiratory disorders NEC

Synonym
Mucus production during mechanical ventilation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: lung characteristics, Mechanical ventilation, mucus

Outcome measures

Primary outcome

To study the differences in PaO2/FiO2 and oxygenation index.

Secondary outcome

To study the differences in EELV.

Study description

Background summary

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.

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) compared with nebulisation of hypertonic or isotonic saline in a heterogeneous group of mechanically ventilated critically ill children. The objective of this study is to test this hypothesis.

Study design

The study is designed as a prospective, randomized interventional pilot study in the period January 2010 - June 2010.

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 nebulisation of hypertonic saline (NaCl 3.0%) 4 ml 4 times a day, or to endotracheal nebulisation of isotonic saline (NaCl 0.9%) 4 ml 4 times a day.

Study burden and risks

Patients have to be disconnected from the ventilator once so that the nebuliser can be placed into the patient circuit. The risks associated with nebulisation of ipratropiumbromide or saline are minimal, the nurses are well-trained to perform these procedures.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)

Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

a) pressure-controlled mechanical ventilation for at least 48 hours
b) pulmonary disease present at or acquired during the first 48 hours of PICU admission (i.e. infection, inflammation, trauma, atelectasis)
c) endotracheal tube leakage < 5% (as measured by the mechanical ventilator)
d) informed consent obtained from parents or legal caretakers
e) presence of indwelling arterial catheter

Exclusion criteria

a) mechanical ventilation less than 48hours or children on high-frequency oscillatory ventilation
b) endotracheal tube leakage > 5%
c) pre-existing congenital heart disease with significant left-to-right shunt
d) haemodynamically or respiratory unstable

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2009
Enrollment:	75

Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Atrovent
Generic name:	Ipratropiumbromide
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	19-01-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2009-015276-10-NL
CCMO	NL29431.042.09