Efficacy of Inhaled RhDNase in Mechanically Ventilated Pediatric Patients with an Atelectasis

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To evaluate the efficacy of inhaled rhDNase in addition to conventional treatment in children with an atelectasis during mechanical ventilation.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Interventional

Summary

ID

NL-OMON30062

Source
ToetsingOnline

Brief title
RhDNase in ventilated pediatric patients

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
atelectasis; partly collapsed lung

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Roche Nederland BV

Intervention

Keyword: atelectasis, child, mechanical ventilation, rhDNase

Outcome measures

Primary outcome

Change from baseline in Chest radiograph-score at 48 hours.

Secondary outcome

Secondary endpoints: Change from baseline in Chest radiograph-score at 24

hours, and change in: ventilatory settings; saturation; blood-gas values and

DNA content in tracheal aspirates; duration of mechanical ventilation.

Study description

Background summary

Atelectasis in children during mechanical ventilation often results from and/or is associated with airway inflammation and airways infection, with an increased influx of inflammatory cells in the airways. Inflammatory cells and damaged epithelial cells degrade, and release DNA in airway mucus resulting in an increased mucus viscosity. Viscous mucus impairs mucociliary clearance, resulting in airways obstruction and impaired resolution of atelectasis.

Study objective

To evaluate the efficacy of inhaled rhDNase in addition to conventional treatment in children with an atelectasis during mechanical ventilation.

Study design

A double blind, randomized, placebo-controlled clinical trial

Intervention

One group receives 2.5 mg of nebulized rhDNase twice daily, and the other group receives 2.5 ml of nebulized isotonic saline twice daily, until extubation, with a maximum of 4 doses. Study medication is given as add-on therapy. The

routine care consists of inhaled isotonic saline, airway clearance therapy, recruitment strategies with the ventilator and bronchoscopy when indicated.

Study burden and risks

Burden: Standard treatment of mechanically ventilated children with an atelectasis consists of (among others) nebulized isotonic saline 4 times daily. During the study period, two nebulizations with isotonic saline will be replaced with study medication. Consequently, the total number of nebulizations will be the same.
After inclusion, two chest radiographs will be made. The only difference with routine patient care is, that during the study period the chest radiographs will be made after a prespecified time-period. In most children with an atelectasis during mechanical ventilation, chest radiographs would have been made anyway to assess resolution or progression of the atelectasis.
A tracheal aspirate is collected by means of tracheal suctioning, a routine-procedure that has to be performed regularly in ventilated children. Material collected during routine tracheal suctioning will be used for analysis.
Blood gas values will be obtained in children with an arterial line only. Therefore no physiological discomfort is to be expected.

Risks: Based on the current literature, it can be concluded that administration of rhDNase in infants and young children on mechanical ventilation for acute respiratory symptoms is safe. Reported side effects of rhDNase, are mild and transient and include pharyngitis, rhinitis and hoarseness. Children who might experience difficulty in coughing up thin mucus theoretically, are excluded from the study (premature infants, paralyzed patients, children with neuromuscular disease).

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

1. Age 0-18 years
2. Mechanical ventilation
3. Presence of an atelectasis on a chest radiograph (CXR)
4. First dose of study medication can be administered within 12 hours after an atelectasis has been diagnosed.

Exclusion criteria

1. Children with neuromuscular disorders and impaired ability to cough; cardiomyopathy; or cystic fibrosis.
2. Post-gestational age < 32 weeks
3. Mechanical ventilation during muscle paralysis
4. Atelectasis due to a bronchoscopically diagnosed:
- foreign body aspiration
- tracheal or bronchial compression by lymph nodes or vessels
5. RhDNase treatment in the previous 48 hours.
6. Clinical condition or ventilator settings that are not compatible with nebulizing medication (according to the responsible physician)
7. Presence of a pneumothorax

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-10-2006
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Pulmozyme
Generic name:	recombinant human deoxyribonuclease (rhDNase; dornase alfa)
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	06-06-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-09-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2006-002098-30-NL
CCMO	NL12247.078.06