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

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RhDNase can liquefy mucus in children with an atelectasis during mechanical ventilation, resulting in improved mucociliary clearance, less mucus retention and less airways obstruction, thereby enhancing the rate of resolution of an atelectasis....

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21415

Bron
NTR

Verkorte titel
N/A

Aandoening

Atelectasis during mechanical ventilation.

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Sophia Children's Hospital. Dr. Molewaterplein 60,
3015 GJ Rotterdam
Overige ondersteuning: Roche BV, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in a Chest radiograph-score (CXR-score) at 48 hours.

Toelichting onderzoek

Achtergrond van het onderzoek

Atelectasis in children during mechanical ventilation often results from and/or is associated with airway inflammation and airways infection, with an increased influx of inflammAatory 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.

We therefore designed a study to evaluate the efficacy of the mucolytic medicine rhDNase in addition to conventional treatment in children with an atelectasis during mechanical ventilation.

Doel van het onderzoek

RhDNase can liquefy mucus in children with an atelectasis during mechanical ventilation, resulting in improved mucociliary clearance, less mucus retention and less airways obstruction, thereby enhancing the rate of resolution of an atelectasis. Moreover we expect the ventilator settings, pulmonary ventilation and ventilation-perfusion mismatch to improve faster, possibly resulting in a shorter time spent on a ventilator and on the ICU.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Intervention group: Twice daily: inhaled rhDNase, 2.5 ml and twice daily 4 ml isotonic saline (NaCl 0.9%), for two days.
Control group: Twice daily: inhaled isotinic saline 2.5 ml and twice daily 4 ml isotonic saline, for two days.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 0-18 years;

2. Mechanical ventilation;

3. Presence of an atelectasis on a chest radiograph;

4. First dose of study medication can be administered preferably within 6 hours (max 12 hours) after an atelectasis has been diagnosed.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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. Recurrent atelectasis due to an anatomical airway-abnormality;

6. RhDNase treatment in the previous 48 hours;

7. Clinical condition or ventilator settings that are not compatible with nebulizing medication (according to the responsible physician);

8. Presence of a pneumothorax;

9. Previous participation in the study.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2006
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	03-07-2006
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	NL715
NTR-old	NTR725
Ander register	: N/A
ISRCTN	ISRCTN07263575

Resultaten

Samenvatting resultaten
N/A