

Efficacy of inhaled recombinant human deoxyribonuclease in mechanically ventilated pediatric patients with an atelectasis

Submission date 28/09/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 28/09/2006	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 06/01/2009	Condition category Respiratory	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR725

Study information

Scientific Title

Study objectives

Recombinant human deoxyribonuclease (rhDNase) can liquefy mucous in children with an atelectasis during mechanical ventilation, resulting in improved mucociliary clearance, less mucous retention and less airway 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 Intensive Care Unit (ICU).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Atelectasis during mechanical ventilation

Interventions

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 isotonic saline 2.5 ml and twice daily 4 ml isotonic saline, for two days.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Recombinant human deoxyribonuclease (rhDNase)

Primary outcome(s)

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

Key secondary outcome(s))

1. Change in a Chest radiograph-score at 24 hours
2. Change in:
 - a. ventilatory settings
 - b. saturation
 - c. blood-gas values
 - d. DeoxyriboNucleic Acid (DNA) content and cytokines in tracheal aspirates
 - e. duration of mechanical ventilation
 - f. length of stay

Completion date

31/12/2010

Eligibility

Key inclusion criteria

1. Aged zero to 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 six hours (maximum 12 hours) after an atelectasis has been diagnosed

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Upper age limit

18 years

Sex

All

Key exclusion criteria

1. Children with neuromuscular disorders and impaired ability to cough, cardiomyopathy, or cystic fibrosis
2. Post-gestational age less than 32 weeks
3. Mechanical ventilation during muscle paralysis
4. Atelectasis due to a bronchoscopically diagnosed:
 - a. foreign body aspiration
 - b. 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 nebulising medication

(according to the responsible physician)

8. Presence of a pneumothorax

9. Previous participation in the study

Date of first enrolment

01/09/2006

Date of final enrolment

31/12/2010

Locations

Countries of recruitment

Netherlands

Study participating centre

Erasmus Medical Center

Rotterdam

Netherlands

3000 CB

Sponsor information

Organisation

Erasmus Medical Center, Sophia Children's Hospital (Netherlands)

ROR

<https://ror.org/047afsm11>

Funder(s)

Funder type

Industry

Funder Name

Roche Nederland BV (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration