

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

Submission date 28/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/01/2009	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/09/2006

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

Age group

Child

Upper age limit

18 Years

Sex

Both

Target number of participants

80

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)

Sponsor details

Dr Molewaterplein 60

Rotterdam

Netherlands

3015 GJ

Sponsor type

Hospital/treatment centre

ROR

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

Funder(s)**Funder type**

Industry

Funder Name

Roche Nederland BV (Netherlands)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration