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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/09/2006	**Overall study status** Completed	
Last Edited 06/01/2009	**Condition category** Respiratory	

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 isotinic 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