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

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON21415

**Source**
NTR

**Brief title**
N/A

**Health condition**

Atelectasis during mechanical ventilation.

### Sponsors and support

**Primary sponsor:** Erasmus Medical Center, Sophia Children's Hospital. Dr. Molewaterplein 60,
3015 GJ Rotterdam
**Source(s) of monetary or material Support:** Roche BV, the Netherlands

### Intervention

### Outcome measures

**Primary outcome**

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

### Secondary outcome

Change in a Chest radiograph-score at 24 hours, and change in: ventilatory settings; saturation; blood-gas values; DNA content and cytokines in tracheal aspirates; duration of mechanical ventilation; length of stay.

## 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 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.

### Study objective

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.

### Study design

N/A

### Intervention

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.

# Contacts

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# Eligibility criteria

## Inclusion criteria

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.

## 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. 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.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-09-2006 |
| Enrollment: | 80 |
| Type: | Actual |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 03-07-2006 |

Application type: First submission

# 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 |
|---|---|
| NTR-new | NL715 |
| NTR-old | NTR725 |
| Other | : N/A |
| ISRCTN | ISRCTN07263575 |

# Study results

**Summary results**
N/A