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# Efficacy of inhaled rhDNase for acute asthma in childhood

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|---|---|---|
| **Submission date**<br>20/12/2005 | **Recruitment status**<br>No longer recruiting | [ ] Prospectively registered<br>[ ] Protocol<br>[ ] Statistical analysis plan<br>[ ] Results<br>[ ] Individual participant data<br>[ ] Record updated in last year |
| **Registration date**<br>20/12/2005 | **Overall study status**<br>Completed | |
| **Last Edited**<br>13/05/2009 | **Condition category**<br>Respiratory | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr R Boogaard

**Contact details**
Erasmus Medical Centre
Sophia Childrens Hospital
Department of Pediatric Pulmonology, SB-2666
P.O. Box 2060
Rotterdam
Netherlands
3000 CB
+31 (0)10 463 6683
r.boogaard@erasmusmc.nl

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
NTR240

# Study information

### Scientific Title

### Study objectives
We hypothesise that rhDNase can liquefy sputum in acute asthma resulting in less airways obstruction, reduced work of breathing, and diminished ventilation-perfusion mismatch, thereby improving symptoms, reducing the number of patients who need to be admitted, and shorten the duration of admission.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Received from the local medical ethics committee

### Study design
Multicentre randomised double-blind placebo-controlled parallel group trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Acute Asthma

### Interventions
One dose of 5 mg rhDNase or one dose of 5 mg placebo in addition to standard care.

### Intervention Type
Drug

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
rhDNase

### Primary outcome measure
Improvement in asthma score 1 hour after intervention.

### Secondary outcome measures
1. Need for hospital admission
2. Duration of hospital admission
3. Asthma score at 2, 6, 12 and 24 hours after intervention
4. Heart rate, respiratory rate and oxygen saturation
5. Need for additional oxygen
6. Number of bronchodilators
7. Doctors visit or readmission and use of rescue bronchodilator aerosol therapy following 72 hours after discharge from EMD
8. Cost-consequence analysis

### Overall study start date
15/09/2005

### Completion date
15/09/2007

## Eligibility

### Key inclusion criteria
Children, aged 2 - 18 years, with acute asthma who require at least two doses of bronchodilators at the Emergency Department.

### Participant type(s)
Patient

### Age group
Child

### Lower age limit
2 Years

### Upper age limit
18 Years

### Sex
Both

### Target number of participants
100

### Key exclusion criteria
1. Dyspnoea due to other causes than asthma
2. Patients with a concurrent chronic pulmonary disease, such as cystic fibrosis (CF), bronchopulmonary dysplasia (BPD)
3. Patients with a symptomatic cardial or neuromuscular disease

**Date of first enrolment**
15/09/2005

**Date of final enrolment**
15/09/2007

# Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**Erasmus Medical Centre**
Rotterdam
Netherlands
3000 CB

# Sponsor information

**Organisation**
Erasmus Medical Centre (Netherlands)

**Sponsor details**
Sophia Children's Hospital
Dr. Molewaterplein 60
Rotterdam
Netherlands
3015 GJ

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.erasmusmc.nl/content/englishindex.htm

**ROR**
https://ror.org/018906e22

# 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