

Efficacy of inhaled rhDNase for acute asthma in childhood

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 13/05/2009	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

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

Protocol serial number
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

Primary study design

Interventional

Study design

Multicentre randomised double-blind placebo-controlled parallel group trial

Study type(s)

Treatment

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(s)

Improvement in asthma score 1 hour after intervention.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

2 Years

Upper age limit

18 Years

Sex

All

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 cardiac 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)

ROR

<https://ror.org/018906e22>

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