Efficacy of inhaled rhDNase for acute asthma in childhood

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration