Efficacy of inhaled rhDNase for acute asthma in childhood.

No registrations found.

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

Summary

ID

NL-OMON29109

Source
Nationaal Trial Register

Brief title
N/A

Health condition

acute childhood asthma

Sponsors and support

Primary sponsor: Erasmus MC, Sophia Children's Hospital
Source(s) of monetary or material Support: Roche

Intervention

Outcome measures

Primary outcome

Improvement in asthma score 1 hour after intervention.

Secondary outcome

1. Need for hospital admission;

2. Duration of hosptial 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. Doctor’s visit or readmission and use of rescue bronchodilator aerosol therapy following 72 hours after discharge from EMD;

8. Cost-consequence analysis.

Study description

Background summary

N/A

Study objective

We hypothesize 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.

Study design

N/A

Intervention

One dose of 5 mg DNase OR one dose of 5 mg placebo in addition to standard care.

Contacts

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Eligibility criteria

Inclusion criteria

Children, aged 2-18 years, with acute asthma who require at least two doses of bronchodilators at the emergency department.

Exclusion criteria

1. Dyspnoea due to other causes than asthma;

2. Patients with a concurrent chronic pulmonary disease, such as CF, BPD;

3. Patients with a symptomatic cardial or neuromuscular disease.

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):	15-09-2005
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion

Date:	06-09-2005
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	NL203
NTR-old	NTR240
Other	: N/A
ISRCTN	ISRCTN81874766

Study results

Summary results
N/A