Efficacy of inhaled DNase in children with an airway malacia and a lowerrespiratory tract infection.

No registrations found.

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

Summary

ID

NL-OMON20292

Source
NTR

Brief title
N/A

Health condition

Tracheobronchomalacia and a lower respiratory tract infection

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Decrease in mean daily Cough Symptom Score (CSS).

Secondary outcome

1. Need for additional antibiotics;

2. Mean daily “cough severity” and “coughability of sputum” (VAS-score);

3. CSS and VAS on each treatment day;

4. Lung function (FEV1, FVC, PEF, MEF25, RINT);

5. Parent’s perception about treatment efficacy;

6. Doctor’s diagnosed end of infection after 1 and 2 weeks treatment.

Study description

Background summary

N/A

Study objective

We hypothesize that DNase improves mucociliary clearance and mucus retention in patients with (trachea)bronchomalacia during a lower respiratory tract infection, resulting in a faster resolution of symptoms and shorter duration of a lower respiratory tract infection.

Study design

N/A

Intervention

Inhaled 2,5 mg DNase or placebo, twice daily for two weeks.

Contacts

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Eligibility criteria

Inclusion criteria

1. Children aged 2-18 years with tracheobronchomalacia (diagnosed bronchoscopically);

2. Symptoms of a lower respiratory tract infection.

Exclusion criteria

1. Indication for a course of antibiotics at presentation (assessed by pediatric pulmonologist);

2. Co-existing chronic pulmonary disease (e.g. cystic fibrosis, broncho pulmonary dysplasia or primary ciliary dyskinesia);

3. History of oesophageal atresia;

4. Neuromuscular disease or psychomotor retardation.

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):	01-09-2005
Enrollment:	40
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	NL204
NTR-old	NTR241
Other	: N/A
ISRCTN	ISRCTN85366144

Study results

Summary results
N/A