

# Efficacy of inhaled DNase in children with an airway malacia and a lower respiratory tract infection

<b>Submission date</b> 20/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/01/2021	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

NTR241

# Study information

## Scientific Title

Efficacy of inhaled DNase in children with an airway malacia and a lower respiratory tract infection

## Study objectives

We hypothesise 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.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Received from the local medical ethics committee

## Study design

Randomised double blind placebo controlled parallel group trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

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

Tracheobronchomalacia, lower respiratory tract disease (LRTD)

## Interventions

Inhaled 2.5 mg DNase or placebo, twice daily for two weeks.

## Intervention Type

Drug

## Phase

Not Applicable

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

DNase

**Primary outcome measure**

Decrease in mean daily Cough Symptom Score (CSS)

**Secondary outcome measures**

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. Parents' perception about treatment efficacy
6. Doctors diagnosed end of infection after 1 and 2 weeks treatment

**Overall study start date**

01/09/2005

**Completion date**

01/09/2007

## **Eligibility**

**Key inclusion criteria**

1. Children aged 2 - 18 years with tracheobronchomalacia (diagnosed bronchoscopically)
2. Symptoms of a lower respiratory tract infection

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

2 Years

**Upper age limit**

18 Years

**Sex**

Both

**Target number of participants**

40

**Total final enrolment**

40

**Key exclusion criteria**

1. Indication for a course of antibiotics at presentation (assessed by paediatric pulmonologist)
2. Co-existing chronic pulmonary disease (eg cystic fibrosis, broncho pulmonary dysplasia or primary ciliary dyskinesia)

3. History of oesophageal atresia
4. Neuromuscular disease or psychomotor retardation

**Date of first enrolment**

01/09/2005

**Date of final enrolment**

01/09/2007

## **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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/10/2009	07/01/2021	Yes	No