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

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 07/01/2021	**Condition category** Respiratory	

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

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?
Results article	results	01/10/2009	07/01/2021	Yes	No