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Efficacy of peripherally targeted inhaled rhDNase for persistent obstructive asthma in childhood

Submission date 09/06/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/06/2006	**Overall study status** Completed	
Last Edited 08/01/2021	**Condition category** Respiratory	

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
2006-002337-20

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2412325-2, NL612, NTR671

Study information

Scientific Title
Efficacy of peripherally targeted inhaled rhDNase for persistent obstructive asthma in childhood

Acronym
IDOL

Study objectives
Recombinant human deoxyribonuclease (rhDNase) improves lung function in children with persistent asthma who have persistent obstructive pulmonary function.

Treatment of mucus impaction is an interesting alternative approach to treating peripheral airflow limitation in asthmatic patients. In severe asthma, dramatic improvement has been described in a few patients after inhalation of the mucolytic rhDNase. In addition, in pathology studies, extensive mucus plugging has been described in asthmatic patients. Based on these findings we think that additional treatment benefit can be obtained when mucus plugging is targeted as part of asthma treatment. Especially for those asthmatic children with persistent peripheral airways obstruction, rhDNase is a well known and safe drug that could be used for this treatment. Therefore we hypothesise that rhDNase has additional effect on lung function in children with persistent asthma who have persistent obstructive pulmonary function.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled 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
Obstructive pulmonary function, asthma

Interventions
Nebulization with rhDNase or placebo once daily (each participant is treated for two weeks with rhDNase and for 2 weeks with placebo)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Recombinant human deoxyribonuclease (rhDNase)

Primary outcome measure
Primary endpoint will be the change in FEF75 as a result of treatment. FEF75 is the most suitable endpoint since it is sensitive to peripheral airways obstruction.

Secondary outcome measures
Secondary endpoints will include:
1. Lung clearance index (LCI) measurements as assessed by multiple breath washout
2. Cumulative symptom diary scores evaluating asthma symptoms in the second week of intervention (e.g. shortness of breath, cough, exercise intolerance, bronchodilator use etc.);
3. Fraction of exhaled nitric oxide (FENO)
4. Other values obtained in the flow volume curve: FEV1, FVC, peak expiratory flow (PEF)

Overall study start date
01/09/2006

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Aged 6 - 18 years
2. Asthma diagnosed according to Global Initiative For Asthma (GINA) guidelines
3. Attending the outpatient clinic for at least one year
4.Treatment with at least 400 mg/day inhaled budesonide or equivalent (dose constant for at least 6 months) and bronchodilators as needed or daily
5. Clinically stable asthma while using a constant dose of Inhaled Corticosteroid (ICS) for at least three months
6. Ability to perform lung function tests (assessed by trained lung function technician)
7. Persistent peripheral airways obstruction as assessed by pulmonary function testing, defined as: dissociation between forced vital capacity (FVC) and FEF75 values: FEF75 at least 20% (absolute % predicted) lower than FVC (FEF = Forced Expiratory Flow rate)
8. FVC within normal limits (for this study defined as FVC >80% predicted)

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
60

Total final enrolment
64

Key exclusion criteria
1. Asthma exacerbation with hospital admission in last three months
2. Intensive care unit (ICU) admission for asthma within the last year
3. Current respiratory tract infection
4. Inability to follow instructions of the investigator
5. Inability to inhale rhDNase
6. Concomitant medical conditions that can affect inhaled treatment (e.g. cleft palate, severe malacia)
7. Neuromuscular disease
8. Smoking

Date of first enrolment
01/09/2006

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
3015 GJ

Sponsor information

Organisation
Erasmus Medical Center (The Netherlands)

Sponsor details
P.O. Box 2040
Rotterdam
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3000 CA

Sponsor type
University/education

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Industry

Funder Name
Roche Nederland BV

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	01/08/2013	08/01/2021	Yes	No