

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

Submission date 09/06/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/06/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/01/2021	Condition category 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
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
Netherlands
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