

DIEPTE-study: DNase Inhalation in CF Exacerbations, Peripherally Targeted

Submission date 14/02/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/02/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/09/2014	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr E.M. Bakker

Contact details
Erasmus Medical Center
Sophia Childrens Hospital
Department of Pediatric Pulmonology (room Sb-2666)
Dr. Molenwaterplein 60
Rotterdam
Netherlands
3015 GJ
+31 (0)10 4636683
e.bakker@erasmusmc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR553; MEC-2005-308

Study information

Scientific Title

Added 24/08/09: Efficacy of RhDNase targeted to the peripheral airways in CF exacerbations. A randomized controlled clinical trial.

Acronym

DIEPTE

Study objectives

Based on earlier studies it is likely that current rhDNase inhalation in children during exacerbations is relatively inefficient. We hypothesize that the efficacy of rhDNase treatment during exacerbations can be improved by targeting the peripheral airways more efficiently in CF. To obtain an optimal lung deposition of rhDNase in children with CF during an exacerbation, the mean particle size of aerosols should be smaller than commonly used for adults. Furthermore, a slow inhalation maneuver should be performed to enable particles to penetrate deeply into the lung. Administration of rhDNase with a MMAD of 3.0 μm and a slow, deep inhalation maneuver using the Akita® nebulizer gives a better peripheral lung deposition in patients with CF.

Our hypothesis is that a better peripheral lung deposition will result in:

1. A bigger improvement in lung function compared to conventional treatment, especially considering the measurements of the peripheral airways: FEF75, FEF75-25 (FEF = Forced Expiratory Flow rate)
2. Reduction of inhomogeneity of ventilation
3. A faster improvement of clinical symptoms

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Randomised double blind active controlled parallel group 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

Cystic Fibrosis (CF)

Interventions

The intervention in this study is the peripheral deposition of rhDNase, using the Akita nebulizer. All patients use DNase as maintenance therapy, thus this medication is not an intervention.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Disease is most prominent in the peripheral airways in CF. Therefore our primary outcome measurement will be focused on the periphery of the lung, using FEF75 and FEF75-25 (assessed by spirometry). FEF75 and FEF75-25 measured on study day 12 (after 7 days of treatment with Akita) is our primary outcome parameter.

Secondary outcome measures

1. Other values obtained in the flow volume curve: FVC, FEV1
2. Lung inhomogeneity measurements
3. Nightly oxygen saturation profile
4. Symptom scores evaluating pulmonary symptoms (e.g. cough, increased sputum)
5. Lung function measurements at discharge
6. Lung function measurements on day 5 (end of run-in) and day 6 (first day of treatment with study drug), to assess a possible short-term effect of the peripherally deposited rhDNase

Overall study start date

01/02/2006

Completion date

01/01/2008

Eligibility

Key inclusion criteria

1. Age between 6 and 18 years old
2. Diagnosis of CF confirmed by sweat-test and/or DNA analysis and/or electro physiology testing (nasal potential difference measurement)
3. Admission to hospital because of a pulmonary exacerbation requiring treatment with iv antibiotics.

The criteria for a pulmonary exacerbation will be based on the definition of exacerbation by Rosenfeld et al. and will include at least three of the following:

- a. Decreased exercise tolerance
 - b. Increased cough
 - c. Increased sputum / chest congestion
 - d. School or work absenteeism
 - e. Decreased appetite
 - f. Increased adventitial sounds on lung examination
 - g. Decrease in FEV1 (% predicted)
4. Enrolment in the study between 1 to 5 days after admission for an exacerbation
 5. Routine treatment with rhDNase once daily, started at least two weeks before enrolment in

the study

6. Ability to perform lung function tests (assessed by trained lung function technician)

7. Lung function: forced vital capacity (FVC) \geq 30% predicted

8. Signed written informed consent

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

40

Key exclusion criteria

1. Inability to follow instructions of the investigator

2. Inability to inhale rhDNase

3. Concomitant medical conditions that effect inhaled treatment (e.g. cleft palate, severe malacia)

4. Pulmonary complications that might put the patient at risk to participate in the study

5. Deterioration primarily related to allergic bronchopulmonary aspergillosis (ABPA)

Date of first enrolment

01/02/2006

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 Centre, Sophia Childrens Hospital (Netherlands)

Sponsor details

Department of Pediatric Pulmonology
Dr Molenwaterplein 60
Rotterdam
Netherlands
3015 GJ

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/047afsm11>

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	01/02/2014		Yes	No