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

Submission date	Recruitment status
14/02/2006	No longer recruiting
Registration date	**Overall study status**
14/02/2006	Completed
Last Edited	**Condition category**
30/09/2014	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
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 um 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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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

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) >/= 30% predicted
8. Signed written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
18 years

Sex
All

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)

ROR
https://ror.org/047afsm11

Funder(s)

Funder type
Industry

Funder Name
Roche Nederland BV (Netherlands)

Results and Publications

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