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A double-blind, randomised, double dummy, cross over, study to assess the difference in efficacy between nebulisation of rhDNase before airway clearance therapy (ACT) versus nebulisation after ACT

Submission date
19/12/2005

Recruitment status
No longer recruiting

Registration date
19/12/2005

Overall study status
Completed

Last Edited
24/08/2009

Condition category
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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR352

Study information

Scientific Title

Study objectives
Inhalation of rhDNase after airway clearance therapy (ACT) increases the expiratory flow at 25% of the actual forced vital capacity (MEF25) compared to inhalation of rhDNase before ACT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Randomised double blind double dummy placebo controlled crossover 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 study was a randomised, double blind, double dummy, cross over design. All subjects nebulized daily both rhDNase (2.5 mg of rhDNase in 2.5 ml buffered solution: 8.77 mg/ml sodium chloride and 0.15 mg/ml calcium chloride) and a placebo (2.5 ml of a buffered solution: 8.77 mg /ml sodium chloride and 0.15 mg/ml calcium chloride) once daily for a period of six weeks. Placebo was similar to rhDNase in both color and taste.
Subjects were randomised to two groups:
Group I used rhDNase 30 minutes before ACT and placebo directly after ACT in the first three

weeks. In the following three weeks rhDNase and placebo were taken in reversed order.
Group II used placebo 30 minutes before ACT and rhDNase after ACT in the first three weeks. In the following three weeks placebo and rhDNase were taken in reversed order.
Patients were asked to carry out their daily routine ACT and not to change their routine technique. The timing during the day of nebulisation and ACT were kept constant throughout the study.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Pulmonary function tests: MEF25

Secondary outcome measures
1. Pulmonary function tests:
1.1. Forced vital capacity (FVC)
1.2. Forced expiratory volume in one second (FEV1)
1.3. Rint
2. Severity of cough with a VCD score
3. Sputum characteristics: amount, viscosity with a visual analogue scale (VAS)

Overall study start date
01/08/2003

Completion date
01/07/2004

Eligibility

Key inclusion criteria
1. Proven CF, as evidenced by an abnormal sweat test or an abnormal rectum potential difference measurement or by the presence of two CF mutations and at least one clinical feature of CF
2. Treated at the Erasmus MC - Sophia, and:
2.1. Five years or older
2.2. Able to perform reproducible manoeuvres for spirometry
2.3. Carrying out daily CPT
2.4. Maintenance treatment with rhDNase for at least one month
2.5. Clinically stable for at least one month (no intravenous antibiotics and/or hospitalisations within one month before enrolment)
3. Willing to participate in and comply with study procedures, and willingness of the parent or guardian and of the subjects >12 years to provide written informed consent

Participant type(s)
Patient

Age group

Child

Lower age limit
5 Years

Sex
Both

Target number of participants
25

Key exclusion criteria
1. Using rhDNase more than once daily
2. Mental retardation
3. Having a history of non-adherence to treatment advice known to the physician

Date of first enrolment
01/08/2003

Date of final enrolment
01/07/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
3015 GJ

Sponsor information

Organisation
Roche Nederland BV (Netherlands)

Sponsor details
P.O. Box 44
Woerden
Netherlands
3440 AA

Sponsor type

Industry

Website
http://www.roche.nl

ROR
https://ror.org/01gcg9888

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	01/07/2007		Yes	No