

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	☐ Prospectively registered
Registration date 19/12/2005	Overall study status Completed	☐ Protocol
Last Edited 24/08/2009	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☒ 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

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

Primary study design

Interventional

Study design

Randomised double blind double dummy placebo controlled crossover group trial

Study type(s)

Treatment

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(s)

Pulmonary function tests: MEF25

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 Years

Sex

All

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)

ROR

<https://ror.org/01gcg9888>

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	01/07/2007		Yes	No