

A double-blind, randomised, double dummy, cross-over, study to assess the difference in efficacy between nebulisation of rhDNase in the morning versus nebulisation before going to sleep

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Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/09/2017	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

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Additional identifiers

Protocol serial number
NTR282

Study information

Scientific Title

A double-blind, randomised, double dummy, cross-over, study to assess the difference in efficacy between nebulisation of rhDNase in the morning versus nebulisation before going to sleep

Study objectives

Inhalation of rhDNase before sleep increases the expiratory flow at 25% of the actual forced vital capacity (MEF25) compared to inhalation of rhDNase in the morning.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Primary study design

Interventional

Study design

Randomised double blind placebo controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cystic fibrosis

Interventions

All subjects nebulised 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 four weeks.

Placebo was similar to rhDNase in both colour and taste. Subjects were randomised to two groups:

1. Group I used rhDNase before going to sleep and the placebo in the morning. Airway clearance techniques are performed 30 minutes after the nebulisation. In the following two rhDNase and placebo were taken in reversed order.
2. Group II used placebo before going to sleep and rhDNase in the morning. Airway clearance techniques are performed 30 minutes after the nebulisation.

In the following two 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.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

rhDNase

Primary outcome(s)

Pulmonary function test: MEF25

Key secondary outcome(s)

1. Pulmonary function tests: FVC, forced expiratory volume in one second (FEV1), Rint
2. Frequency and duration of coughing measured with audio recording
3. Oxygenation at night recording transcutaneous oxygen saturation; percentage with saturation below 95%
4. Severity of cough with a verbal category descriptive (VCD) score
5. Sputum characteristics: amount, viscosity with a visual analogue scale (VAS) score
6. Quality of sleep and appetite with a VAS score
7. Presence of morning sickness

Completion date

01/02/2006

Eligibility**Key inclusion criteria**

1. Proven cystic fibrosis (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 Medical Centre - Sophia
3. Five years and older
4. Able to perform reproducible manoeuvres for spirometry
5. Maintenance treatment with rhDNase for at least one month
6. Clinically stable for at least one month (no intravenous antibiotics and/or hospitalisations within one month before enrolment)
7. Willing to participate in and comply with study procedures, and willingness of the parent or guardian and subjects greater than 12 years to provide written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

1. Forced vital capacity (FVC) less than 40%
2. Using rhDNase more than once daily

3. Mentally retarded
4. History of non-adherence to treatment advice known to the physician

Date of first enrolment

01/09/2004

Date of final enrolment

01/02/2006

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	01/10/2007		Yes	No