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# 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

**Submission date**
20/12/2005

**Recruitment status**
No longer recruiting

**Registration date**
20/12/2005

**Overall study status**
Completed

**Last Edited**
13/09/2017

**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
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

### Study design
Randomised double blind placebo controlled 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

### 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 measure
Pulmonary function test: MEF25

### Secondary outcome measures
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

### Overall study start date
01/09/2004

### 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

### Age group
Other

### Sex
Both

### Target number of participants
25

### 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)

### Sponsor details

Postbus 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 | 01/10/2007 | | Yes | No |