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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20146

Source
NTR

Brief title
N/A

Health condition

Cystic Fibrosis.

Sponsors and support

Primary sponsor: Roche Nederland BV
PO Box 44
3440 AA WOERDEN
The Netherlands
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Pulmonary function test: MEF25.

Secondary outcome

1. Pulmonary function tests: FVC, FEV1, Rint;

2. Frequency and duration of coughing measured with audiorecording;

3. Oxygenation at night recording transcutaneous oxygen saturation;
percentage with saturation below 95%;

4. Severity of cough with a VCD score;

5. Sputum characteristics: amount, viscosity with a VAS-score;

6. Quality of sleep and appetite with a VAS-score;

7. Presence of morning sickness.

Study description

Background summary

Though the effectiveness of rhDNase is well established, little research has been carried out to determine the optimal time relation between rhDNase and ACT.

Objective:

To assess the difference in lung function between nebulisation of rhDNase before going to sleep versus nebulisation in the morning.

Methods:

The study is randomized, double blind, double dummy, cross over design.
- Inclusion criteria were CF, stable clinical condition and rhDNase maintenance therapy.

Randomisation:

- Group I: Week 1-2, inhalation of rhDNase before going to sleep, and placebo in the morning. The reversed protocol was performed during week 3-4.

- Group II: Reversed sequence. Patients continued their daily routine ACT; which was performed 30 minutes after the nebulisation in the morning.

Primary endpoint:

MEF25. Flow volume manoeuvre and Rinte are measured on day 0, 7, 14, 21, 28. The children score quality of sleep, morning sickness, cough and sputum production daily on diary cards in week 2 and 4. Cough frequency and oxygen saturation are mesured on day 7, 14, 21 and 28.

Study objective

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.

Study design

N/A

Intervention

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 four weeks.
Placebo was similar to rhDNase in both color and taste. Subjects were randomized to two groups.
- Group I used rhDNase before going to sleep and the placebo in the morning. Airway clearance techniques are performed 30 mnutes after the nebulisation. In the following two rhDNase and placebo were taken in reversed order.
- Group II used placebo before going to sleep and rhDNase in the morning. Airway clearance

techniques are performed 30 mnutes 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.

Contacts

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Eligibility criteria

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

a. Five years and older;

b. Able to perform reproducible manoeuvres for spirometry;

c. Maintenance treatment with rhDNase for at least one month

d. Clinically stable for at least one month (no intravenous antibiotics and / or hospitalizations within one month before enrolment);

3. Willing to participate in and comply with study procedures, and willingness of the parent or guardian and subjects >12 years to provide written informed consent.

Exclusion criteria

Admission:

1. FVC <40%;

2. Using rhDNase more than once daily;

3. Mental retardation;

4. Having a history of non-adherence to treatment advice known to the physician.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2004
Enrollment:	25
Type:	Actual

Ethics review

Positive opinion

Date:	09-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL244
NTR-old	NTR282
Other	: N/A
ISRCTN	ISRCTN74815264

Study results

Summary results
Eur Respir J. 2007 Oct;30(4):763-8. Epub 2007 Jun 27.