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

No registrations found.

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

Summary

ID

NL-OMON25167

Source
NTR

Brief title
N/A

Health condition

Cysic 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 tests: MEF25.

Secondary outcome

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

2. Severity of cough with a VCD score;

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

Study description

Background summary

Introduction:
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 ACT versus nebulisation after ACT.

Methods:
The study was a randomized, double blind, double dummy, cross over design. Inclusion criteria were CF, stable clinical condition and rhDNase maintenance therapy.
Randomisation:
- Group I: Week 1-3, inhalation of rhDNase 30 minutes before, and placebo directly after ACT. The reversed protocol was performed during week 4-6.
- Group II: Reversed sequence. Patients continued their daily routine ACT.
Primary endpoint:
MEF25. Flow volume manoeuvre and Rinte were measured on day 0, 14, 21, 35 and 42. The children scored cough and sputum production daily on diary cards in week 3 and 6.

Study objective

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

ACT.

Study design

N/A

Intervention

The study was a randomized, 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 randomized 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. (Figure 1)
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.

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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 or older;

b. Able to perform reproducible manoeuvres for spirometry;

c. Carrying out daily CPT;

d. Maintenance treatment with rhDNase for at least one month;

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

4. 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.

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.

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):	01-08-2003
Enrollment:	25
Type:	Actual

Ethics review

Positive opinion

Date:	12-09-2005
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	NL314

Register	ID
NTR-old	NTR352
Other	: N/A
ISRCTN	ISRCTN87248226

Study results

Summary results

Pediatr Pulmonol. 2007 Jul;42(7):624-30.

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