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.

Gepubliceerd: 12-09-2005 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25167

Bron
NTR

Verkorte titel
N/A

Aandoening

Cysic Fibrosis.

Ondersteuning

Primaire sponsor: Roche Nederland BV
PO box 44
3440 AA WOERDEN
The Netherlands

Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pulmonary function tests: MEF25.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Using rhDNase more than once daily;

2. Mental retardation;

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-08-2003
Aantal proefpersonen:	25
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	12-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL314

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

Resultaten

Samenvatting resultaten

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

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