

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.

Gepubliceerd: 09-09-2005 Laatste bijgewerkt: 13-12-2022

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.

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

Samenvatting

ID

NL-OMON20146

Bron

NTR

Verkorte titel

N/A

Aandoening

Cystic 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 test: MEF25.

Toelichting onderzoek

Achtergrond van het onderzoek

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 measured on day 7, 14, 21 and 28.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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 minutes after the nebulisation. In the following two weeks 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 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.

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 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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2004
Aantal proefpersonen:	25
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	09-09-2005
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	NL244
NTR-old	NTR282
Ander register	: N/A
ISRCTN	ISRCTN74815264

Resultaten

Samenvatting resultaten

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