Saline hypertonic in preschoolers and lung structure as measured by computed tomography.

Gepubliceerd: 29-09-2015 Laatst bijgewerkt: 18-08-2022

The primary hypothesis is that HS will reduce structural lung disease as assessed by the PRAGMA-CF computed tomography score relative to IS during the 48 week treatment period.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28150

Bron
Nationaal Trial Register

Verkorte titel
Ship-CT study

Aandoening

Cystic Fibrosis (CF)

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: SPONSOR: Cystic Fibrosis Foundation Therapeutics, Inc., 6931 Arlington Road, Bethesda, Maryland 20814

LOCAL SPONSOR AUSTRALIA:
Telethon Kids Institute
PO Box 855, West Perth, WA, 6872 Australia

LOCAL SPONSOR EUROPE:
Erasmus Medical Centre
Erasmus University

Rotterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The difference in PRAGMA-CF %Dis between HS and IS study arm at end of study (48 weeks), measured from standardized chest CT.

Toelichting onderzoek

Doel van het onderzoek

The primary hypothesis is that HS will reduce structural lung disease as assessed by the PRAGMA-CF computed tomography score relative to IS during the 48 week treatment period.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Test drug, dose and mode of administration:

7% Hypertonic Saline (HS).

In Australia this will be supplied in 10mL glass vials packed 5 vials per pack in plain white packaging, and manufactured by Phebra.

In Europe this will be supplied in 5 ml glass ampoules, 7 vials per pack, and manufactured by Apotheek A15.

4ml of HS will be administered via inhalation twice daily for 48 weeks. The delivery system is a PARI Sprint Junior nebulizer with a PARI Baby face mask or mouthpiece driven by a PARI compressor (PARI Vios® Pro in USA, PARI BOY SX in Australia and Europe).

Control, dose and mode of administration:

0.9% Isotonic Saline (IS).

In Australia this will be supplied in 10mL glass vials packed 5 vials per pack in plain white packaging, and manufactured by Phebra.

In Europe this will be supplied in 5 ml glass ampoules, 7 vials per pack, and manufactured by Apotheek A15. The delivery system is the same as that for the test product. 4 ml of IS will be administered via inhalation twice daily for 48 weeks

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Diagnosis of CF as evidenced by one or more clinical feature consistent with the CF phenotype or positive CF newborn screen AND one or more of the following criteria:

a) A documented sweat chloride ¡Ý 60 mEq/L by quantitative pilocarpine iontophoresis (QPIT)

b) A documented genotype with two disease-causing mutations in the CFTR gene

2. Informed consent by parent or legal guardian

3. Age ¡Ý 36 months and ¡Ü72 months at Screening visit
4. Ability to comply with medication use, study visits and study procedures as judged by the site investigator

5. Ability to execute a technician controlled or spirometer controlled chest CT scan

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Chest CT within 8 months prior to the Screening visit

2. Acute intercurrent respiratory infection, defined as an increase in cough, wheezing, or respiratory rate with onset within 3 weeks preceding Screening or Enrolment visit

3. Acute wheezing at Screening or Enrollment visit

4. Oxygen saturation < 95% (<90% at centres above 4000 feet elevation) at Screening or Enrollment visit

5. Other major organ dysfunction, excluding pancreatic dysfunction

6. Physical findings that would compromise the safety of the participant or the quality of the study data as determined by site investigator

7. Investigational drug use within 30 days prior to Screening or Enrolment visit

8. Treatment with inhaled hypertonic saline at any concentration within 30 days prior to Screening or Enrolment visit

9. Start of any additional inhaled saline solution at any concentration, or other hydrating agent such as mannitol or mucolytic drug such as dornase alpha within 30 days prior or following the Screening or Enrollment visit

10. Chronic lung disease not related to CF

11. Inability to tolerate first dose of study treatment at the Enrolment visit

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2016
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL5245
NTR-old	NTR5502
Ander register	EudraCT : 2015-004143-39

Resultaten