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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28150

Source
Nationaal Trial Register

Brief title
Ship-CT study

Health condition

Cystic Fibrosis (CF)

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: 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

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Longitudinal change in airway disease (%Dis), bronchiectasis (%Bx) and trapped air (%TA), as well as the proportion of patients with bronchiectasis progression, from baseline to end of study as established by PRAGMA-CF and Airway dimensions as measured using the AA method from chest CT

• on expiratory or spontaneous breathing CTs

• Longitudinal change in LCI, measured by N2 MBW, from baseline to 48 weeks between treatment arms.

• Protocol-defined pulmonary exacerbation rate

• Modified parent-reported CFQ-R for preschool children, a CF-specific measure of health related quality of life (excluding European sites).

Study description

Study objective

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.

Study design

N/A

Intervention

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

Contacts

Public
Erasmus Medical Center, Sophia Children’s Hospital Rotterdam, Department of Pediatric Pulmonology,
Dr. Molewaterplein 60
H.A.W.M. Tiddens
Dr. Molewaterplein 60
Rotterdam 3015 GJ
The Netherlands
+31 (0)10 4636690 / +31 (0)10 4636363 (general)
Scientific
Erasmus Medical Center, Sophia Children’s Hospital Rotterdam, Department of Pediatric Pulmonology,
Dr. Molewaterplein 60
H.A.W.M. Tiddens
Dr. Molewaterplein 60
Rotterdam 3015 GJ
The Netherlands
+31 (0)10 4636690 / +31 (0)10 4636363 (general)

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2016
Enrollment:	120
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL5245
NTR-old	NTR5502
Other	EudraCT : 2015-004143-39

Study results