Contrast enhanced Magnetic Resonance Imaging of the lungs in children with Cystic Fibrosis.

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To assess whether the GdMRI can fit in the annual check up.To assess whether the GdMRI is sensitive to monitor and follow up on the peripheral bronchiectasis and areas of hypoperfusion. To compare the distribution and volume of hypo perfusion on...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON31207

Source
ToetsingOnline

Brief title
Gd-MRI in CF.

Condition

- Respiratory disorders NEC

Synonym
mucoviscoidosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: MRI CF contrast longen

Outcome measures

Primary outcome

The ability of the radiologist and CF team to identify areas of the lung that

are hypo perfused on the Gd-MRI relative to the proton-MRI.

The distribution and volume of hypo perfused lung on the Gd-MRI will be

compared to the distribution of trapped air on the proton-MRI and with the

chest CT made in the previous year.

After completion of the study all CTs and Gd-MRIs will be scored anonymous and

in random order using a semi quantitative scoring system.

Secondary outcome

The ability of the radiologist and CF team to identify progression of

peripheral bronchiectasis compared to the CT made in the previous year.

Study description

Background summary

Traditionally pulmonary function tests have an important place in the monitoring of CF lung disease. A major disadvantage is that they are not sensitive to localized severe structural changes. CT is the most sensitive technique to detect structural lung changes in CF such as bronchiectasis and trapped air. A major disadvantage of CT is that it exposes the patient to ionising radiation. Therefore we have restricted the use of CT to one examination every two years. Proton-MRI was introduced in 2006 to fill in the gap between the bi-annual CT evaluations. With proton-MRI central bronchiectasis can well be tracked. Unfortunately, the detection of peripheral bronchiectasis and trapped air is of relative poor quality. Fortunate, trapped air on proton-MRI can be visualized by looking at lung perfusion since persisting hypoventilation of areas of the lung result in matched hypo

perfusion. Lung perfusion can be visualized by MRI using intravenously injected contrast agent Gadolinium.

Study objective

To assess whether the GdMRI can fit in the annual check up.
To assess whether the GdMRI is sensitive to monitor and follow up on the peripheral bronchiectasis and areas of hypoperfusion. To compare the distribution and volume of hypo perfusion on expiratory contrast enhanced Gd-MRI to the areas of trapped air on the routine proton MRI and on the CTscan of the previous yaer. When this is the case Gd-MRI will be added as a routine to the MRI protocol used in CF patients. To compare the distribution and volume of hypo perfusion on expiratory contrast enhanced Gd-MRI to PFTs parameters of peripheral airway disease (FEF75, FEF25-75, LCI)

Study design

Parents from patients who are planned for a proton-MRI will be informed about the study If the patient and parents agree to participate in this study the Gd-MRI will be made on the day of the annual check up after the proton-MRI. The routine annual blood withdrawal will be done after insertion of a peripheral catheter. The catheter will be flushed and immobilized. During the Gd-MRI the catheter will be used to inject the Gadolinium.Directly after the MRI investigation the catheter will be removed.

Study burden and risks

Instead of a routine blood draw by needle a intravenous catheter will be inserted, this is a more painful procedure therefore the patient will be offered Emla® cream. The catheter will be used during the MRI procedure for the injection of Gd. The Gd-MRI sequences will be added to the routine proton-MRI protocol. This will require little extra time (10min).
Gadolinium is considered a safe contrast agent with a low incidence of complications. The major complication that occurs is an allergic reaction. Patients with severe asthma and/or allergies and patients with a known allergic reaction on Gadolinium will be excluded. Also patients with end stage renal disease will be excluded.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

inclusion criteria: signed informed consent, able to comply with protocol requirements, diagnosis of CF confirmed, age 6-18 years, stable condition, ability to perform lung function tests and breathhold manoeuvres, CT in the year before the MRI.

Exclusion criteria

Exclusion criteria: inability to follow instructions of the investigator, current respiratory infection requiring IV antibiotics, pulmonary complications that might put patient at risk to participate , claustrophobia, history of anaphylactic reaction on contrast agent, any clinical condition which, according to the treating physician, might put patient at risk, severe asthma and/or severe allergies as determined by physician.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-12-2007
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	10-10-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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

CCMO	NL17489.078.07
Other	trial is aangemeld bij ISRTCN helaas identificatienr nog niet ontvangen, nummer wordt u nagezonden.