Optimizing lung imaging in people with Ataxia Telangiectasia applying improved MRI techniques.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neurological disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON44255

Source
ToetsingOnline

Brief title
MRI in AT (MINAT study).

Condition

- Neurological disorders NEC
- Respiratory disorders NEC

Synonym
Ataxia telangiectasia (AT); Louis-Bar disease

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Action for A-T research grant

Intervention

Keyword: Ataxia Telangiectasia, Chronic lung disease, Magnetic Resonance Imaging

Outcome measures

Primary outcome

The study result/product will be a reliable and useful imaging technique of the lungs without having to use ionising radiation in AT patients. This will be scored by two experienced radiologists. The main quality criteria are the ability to detect:

* Bronchiectasis

* Atelectasis and/or consolidation

* Emphysema

* Other lungabnormalities

Secondary outcome

Not applicable.

Study description

Background summary

Almost all children and adults with Ataxia Telangiectasia (AT) suffer from recurrent or chronic lung disorders. This is due to their muscle weakness, immunological disorders and increased frequency of oncological disorders and interstitial lung disease.
Respiratory morbidity constitutes a large burden for these patients and their families or caretakers, may cause severe symptoms and is the main cause of death. In order to improve treatment, it is necessary to be able to diagnose and monitor the condition of the lung. Lung function measurements are too difficult to carry out reliably for many people with AT, and imaging of the lungs with conventional radiology of the chest involves ionizing radiation that

should be avoided whenever possible because patients with AT suffer from DNA repair disorders, increasing the risk of developing malignancies. Magnetic Resonance Imaging (MRI) does not involve ionizing radiation and improved MRI of the lungs would be the ideal tool to obtain reliable structural information about the lungs. However, MRI was not very suitable for lung imaging till recently because of poor resolution and contrasts, MRI is not a quick procedure and patients with AT often have uncoordinated movements that preclude optimal imaging.

Study objective

The purpose of this research project is to improve the overall quality and resolution of the MRI images, to correct for movement effects during the procedure and to speed up the investigation. The goal is to enhance and standardize a technique suitable for routine clinical care of patients with AT, also the severe and the young.

Study design

This is an observational study in 2 parts in which we: (part 1) validate and optimize the quality of MRI imaging of the lungs by comparisons with imaging using CT scan in a group of patients 6 years of age and older with various chronic lung diseases (mainly with Cystic Fibrosis) who undergo a diagnostic CT scan for their routine patient care; (2) improve the resolution of MRI imaging of the lungs in patients with Ataxia Telangiectasia (AT) who exhibit involuntary movements that complicate imaging.

Study burden and risks

Prior to the study described here, an MRI protocol for lung imaging will be developed and optimized on a group of adult healthy volunteers and adult fairly healthy patients with lung diseases. In this way we expect to diminish the burden on the paediatric patients.
However, as the group of AT patient consists mainly of children, the final version of the MRI lung protocol has to be optimized in children and adolescents in which a smaller field of view is necessary and MR relaxation times of tissue differ from those of adults.

The burden of patients who undergo one additional MR imaging session are the duration of the procedure (approximately half an hour) and the noise of the scanner. To minimize this burden, proper ear protection will be used and, if needed, some children will be trained in the *dummy MRI system* present at the department of Paediatrics. There are no risks involved. There are no additional hospital visits involved since MR and CT imaging in patients with chronic lung disease (study part 1) will be conducted on the same day.

The benefit of the patients who participate in the study will be that after the completion of the study, they will benefit themselves from the enhanced thorax imaging that is then possible with MRI, instead of being exposed to ionizing radiation. This applies both to patients with and without AT, since in both populations, less ionizing radiation will be applied for their routine patient care after completion of this study. Especially for patients with AT (study part 2), this will be a new and unique development in imaging and monitoring lung disease without using ionizing radiation. This is very relevant for these patients since they easily develop malignancies when exposed to ionizing radiation as used by the CT scan and Chest X-ray (due to their impaired DNA repair capacity).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Elderly (65 years and older)

Inclusion criteria

Part 1: Patients with chronic lung diseases other than AT: These are patients with a chronic lung disease (such as bronchiectasis, or Cystic Fibrosis) for whom a routine CT * scan of the lungs is planned as part of routine patient care, for their follow-up and treatment of their illness. In addition to the CT-scan these patients (children and adults) will be asked to participate by obtaining MRI imaging of the lungs. Children from the age of 6 years on will be recruited.
Part 2: During this part of the study, MRI images will be obtained in patients with AT. Special attention will be payed to correcting for moving artefacts, and to optimization of the resolution of the technique. Subjects who are quite young and/or uncomfortable in a tunnel will be trained using our *dummy MRI*, that is available near the Radiology Department. In those children, a simulation MRI investigation will be tested and conducted by specialized nurses. From the second year on, we will start investigate children and adults with AT using MRI.

Exclusion criteria

The usual general exclusion criteria for MRI investigations in clinical practice, including claustrofobia.
Extreme fatigue in AT patients.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-03-2018
Enrollment:	80

Type:	Actual

Ethics review

Approved WMO Date:	07-12-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-11-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-11-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL62028.091.17