Congenital Lung Abnormalities on MRI

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

Summary

ID

NL-OMON50335

Source
ToetsingOnline

Brief title
CLAM

Condition

- Respiratory disorders congenital
- Congenital respiratory tract disorders

Synonym
congenital cystic lung disease, Congenital pulmonary airway malformation

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Stichting Vrienden van Sophia

Intervention

Keyword: Cine, Congenital, Cystic Adenomatoid Malformation of Lung, Magnetic Resonance

Imaging

Outcome measures

Primary outcome

The main study endpoints are the MRI features of the lungs both before and after resection of CPAM and its correlation to lung function.

Secondary outcome

Secondary endpoint is the MRI scan protocol in which optimal imaging of lung parenchyma and abnormalities is achieved. Furthermore, the difference in lung function between surgically and conservatively treated patients as well as their relation to imaging characteristics including volume of the abnormality.

Study description

Background summary

Congenital lung abnormalities (CLA) are rare developmental anomalies which are increasingly being detected by prenatal ultrasonography. CPAM*s are the most prevalent abnormality comprising up to 30% of all CLA*s. They are cystic lung tissue malformations with pulmonary vascularization and an intact but abnormal connection to the tracheobronchial tree. In symptomatic patient a surgical resection is warranted but there is currently no consensus on the best mode of treatment in asymptomatic patients. They are either operated or undergo structured long-term follow-up. Computed tomography (CT) is the postnatal diagnostic method of choice and most frequently used imaging modality for long-term monitoring and as pre-operative workup because of high accuracy and its excellent spatial resolution. Due to the exposure of ionizing radiation its use should be limited. With recent technological advances allowing shorter scan times, MRI is increasingly being used in diagnosis of various childhood lung diseases including CLA*s, avoiding radiation exposure. Furthermore, the use of functional MRI techniques have added value due to real time imaging. However, there is still lack of information on the optimal scan protocol in CLA and the appearance of these parenchymal anomalies on MRI. As follow-up is warranted in CPAM, a reduction in unnecessary radiation exposure may be achieved by using MRI instead of CT-imaging. Because disease behavior is unknown, standardized follow up is done adhering to general protocols. By imaging these patients the

course of the disease may be monitored and follow up may be adapted to these findings.

Study objective

Our main objective is to validate a MRI scan protocol for imaging parenchymal abnormalities in CPAM and describe the appearance of these abnormalities on MRI. Furthermore, we want to image postoperative changes in developing lungs of patients operated for CPAM. Correlation between imaging and lung function findings to each other and clinical parameters is a secondary objective.

Study design

Prospective, cross-sectional study of patients with (history of) CPAM conducted at the Erasmus MC * Sophia Children*s Hospital. All subjects are enrolled in a prospective follow-up program in children with congenital anomalies (CHIL, surgical long-term follow-up). Each included patient will visit the hospital once during which a lung function test will be obtained and a subsequent MRI will be made after obtaining signed informed consent.

Study burden and risks

CPAM is a rare disease and the majority of asymptomatic cases have been detected since the introduction of the prenatal structured ultrasound in the last two decades. As this is the case, the majority of unresected CPAM cases are still in the pediatric age range. As the general practice is to avoid/minimize radiation exposure in the pediatric population, little is known about structural changes of developing lungs after a lung resection. Information obtained from these subjects might possibly aid in further research on lung resection procedures and subsequent follow-up in the pediatric population. MRI is considered a safe imaging technique with no exposure to ionizing radiation. Other than anxiety due to claustrophobia and noise produced by the MRI, no other side-effects are known. Our MRI scan protocol is focused on obtaining the most clear pictures in the least amount of time not exceeding 45 minutes in total.

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

- Radiological or if resected pathological diagnosis of CPAM
- Enrolment in CHIL follow-up program
- Age * 8 years and < 18 years at the start of the study
- Signed informed consent by parents and/or patient

Exclusion criteria

- Contra- indications for MRI
- Cognitive impairment preventing adherence to breathing instructions
- Presence of associated anomalies in chest cavity which might skew results according to primary physician
- Claustrofobia

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):	13-10-2020
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO Date:	07-08-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	27-07-2020
Application type:	Amendment
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

ID: 22444

Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL65930.078.18
OMON	NL-OMON22444