Congenital Lung Abnormalities on MRI

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22444

Source
Nationaal Trial Register

Brief title
CLAM

Health condition

Magnetic Resonance Imaging, Cine
Cystic Adenomatoid Malformation of Lung, Congenital

Sponsors and support

Primary sponsor: Erasmus Medical Center, Sophia Children's Hospital
Source(s) of monetary or material Support: Vrienden van Sophia

Intervention

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

Rationale: 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.

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 population: All patients between the ages of 8 and 18 years enrolled in the surgical long-term follow-up programme of the Erasmus MC – Sophia Children's Hospital (CHIL) diagnosed with CPAM will be included when meeting inclusion and exclusion criteria.

Intervention : Not applicable

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

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Study design

MRI and lungfunction test will be obtained at a single timepoint

Intervention

MRI

Lungfunction test

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

- 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 non invasive
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2018
Enrollment:	42
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 50335
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6943
NTR-old	NTR7199
CCMO	NL65930.078.18
OMON	NL-OMON50335

Study results