# Congenital Lung Abnormalities on MRI

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| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON22444

**Bron**
Nationaal Trial Register

**Verkorte titel**
CLAM

**Aandoening**

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

### Ondersteuning

**Primaire sponsor:** Erasmus Medical Center, Sophia Children's Hospital
**Overige ondersteuning:** Vrienden van Sophia

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

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

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

**Onderzoeksopzet**

MRI and lungfunction test will be obtained at a single timepoint

**Onderzoeksproduct en/of interventie**

MRI

Lungfunction test

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Cross-over |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-10-2018 |
| Aantal proefpersonen: | 42 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50335
Bron: ToetsingOnline
Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

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

## Resultaten