

Growing up after surgery for Congenital Diaphragmatic Hernia (CDH): Problems for life? A study to evaluate optimal medical and psychosocial care in CDH Follow-Up till adulthood (CDH-FU)

No registrations found.

| | |
|------------------------------|----------------------------|
| Ethical review | Positive opinion |
| Status | Recruiting |
| Health condition type | - |
| Study type | Observational non invasive |

Summary

ID

NL-OMON29669

Source

NTR

Brief title

CHD-FU

Health condition

CHD at birth

Sponsors and support

Primary sponsor: ErasmusMC

Source(s) of monetary or material Support: Vaillantfonds, Innovatiefonds, CHD-UK

Intervention

Outcome measures

Primary outcome

Reduced maximal exercise capacity (VO₂max)

Secondary outcome

Persistent pulmonary morbidity as reflected by:

- Irreversible small airway obstruction (FEV₁ before and after bronchodilation, FEF₂₅₋₇₅ before and after bronchodilatation)
- Reduced diffusion capacity of the lungs after correction for total lung capacity (DLOcc, KCORCL)
- Abnormal pulmonary structure on chest CT (separate volume fractions of total airways disease (%Dis), and trapped air (%TA))
- Abnormal morphology of the repaired diaphragm
- Echocardiographic signs of pulmonary hypertension and ventricular dysfunction⁴
- Total and subdomain scores participation (IPA)
- Health status (physical and mental scale of RAND-36)
- Total score fatigue (FSS)
- Dyspnea score
- Total score and domain scores social emotional wellbeing (scores on ASR)
- Airway artery (AA) dimensions using the AA-method
- Growth and nutritional status (BOD-POD)

Study description

Background summary

To evaluate persisting pulmonary morbidity and echocardiographic signs of pulmonary hypertension in young adults born with CDH that interfere with physical fitness and participation in society.

Secondary Objective(s): To evaluate fatigue, social-emotional wellbeing, nutritional and health status, and participation in society.

Study objective

to improve the medical care on long term follow up

Study design

1 study day for all the test, 1 meeting for discuss the results

Intervention

ECG, BOD-POD, lung-functiontest, questionnaires, CT and physical examination

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

- ☐ Diagnosed with CDH within the first 7 days of life and alive at time of recruitment
- ☐ Born between 1989 and 2001 (patient recruitment is ongoing in 2019; minimum age is 18 years)
- ☐ Sufficient intellectual capacities and/or command of the Dutch language to understand instructions
- ☐ Clinically stable for > 3 weeks

Exclusion criteria

- ☐ Serious comorbidity that might affect assessments (e.g. serious neurological comorbidity)

Study design

Design

| | |
|---------------------|----------------------------|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |

Control: N/A , unknown

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 18-04-2019

Enrollment: 50

Type: Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description

NA

Ethics review

Positive opinion

Date: 18-04-2019

Application type: First submission

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

NTR-new

NL7688

Other

METC Erasmus MC : METC 2018-1588

Study results