Growing up after surgery for congenital diaphragmatic hernia (CDH): Problems for life? A study to evaluate optimal medical and psychosocial care in CDH up till adulthood (CDH-FU)

Published: 11-01-2019
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Primary Objective: 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...

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

Summary

ID

NL-OMON49276

Source
ToetsingOnline

Brief title
Physical and psychosocial evaluation in adults born with CDH

Condition

- Respiratory disorders congenital
- Cognitive and attention disorders and disturbances
- Pulmonary vascular disorders

Synonym
Congenital diafragmatic hernia

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Innovatiefonds;Vaillantfonds

Intervention

Keyword: Congenital diaphragmatic hernia, long term follow up, Psychosocial effects, Pulmonary morbidity

Outcome measures

Primary 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)

* Reduced maximal exercise capacity (VO2max)

* Abnormal pulmonary structure on chest CT (separate volume fractions of total

airways disease (%Dis), and trapped air (%TA))

Secondary outcome

* 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

Information on outcomes in (young) adults born with CDH is scarce. Based on the studies in adults born before extracorporeal membrane oxygenation (ECMO) was available we have the following assumptions and hypothesis: The population of CDH patients that survives nowadays has more severe lung hypoplasia than those who survived in the 1980s before ECMO became available. Our hypothesis is that the population of young adults who were treated for CDH in an era with improved intensive care and use of ECMO, have persistent pulmonary morbidity and microstructural changes in the lungs with obstructive lung function, decreased diffusion capacity of the lungs, signs of pulmonary hypertension, and diminished maximal exercise capacity. Moreover, we assume that they suffer more frequently from fatigue, poor growth, altered nutritional status, and social-emotional problems and that their health status and participation is reduced compared to that of healthy peers.

Study objective

Primary Objective: 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 design

Observational, cross-sectional cohort study.

Study burden and risks

Participants are being asked to come one full day for assessments and physical examination and are being offered a second visit to the outpatient clinic of the hospital or a phone call to discuss individual results. Additional questionnaires will take approximately one hour to fill in at home or otherwise during the break between the other assessments. Assessments include lung function measurement before and after bronchodilatation, maximal exercise test, echocardiogram and electrocardiogram and a CT scan and questionnaires. Bronchodilatation is performed using 12 mcg of formoterol which is the normal

dose used in routine patient care and considered of low risk. The lowest radiation dose will be used to obtain a CT of diagnostic quality. The risks related to this protocol are considered low. Benefits for the participant are careful evaluation, individual results and advice for future care provided by a medical specialist experienced in CDH. The results of this study will contribute to the evidence for optimal care of CDH patients in adolescence and adulthood.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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 invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-05-2020
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	11-01-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-06-2020

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

No registrations found.

In other registers

Register	ID
CCMO	NL67096.078.18