Long-term lung function, exercise endurance, participation and quality of life in congenital diaphragmatic hernia

Published: 12-06-2007
Last updated: 08-05-2024

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

Summary

ID

NL-OMON31375

Source
ToetsingOnline

Brief title
Lung function and exercise endurance in congenital diaphragmatic hernia

Condition

- Respiratory disorders congenital

Synonym
congenital diaphragmatic hernia, diaphragmatic defect

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: subsidie verkregen van Stichting Nuts-Ohra

Intervention

Keyword: congenital diaphragmatic hernia, exercise endurance, long-term, lung function

Outcome measures

Primary outcome

Lung function parameters

o Lung volumes and lung clearance index

o Airway patency

o Diffusion capacity of the lung

o Exhalized NO-concentration

Exercise endurance

o Cardiovascular and pulmonary function dependent exercise endurance

o Neuromuscular strength

o Body composition

Secondary outcome

-Fatigue

-Pulmonary problems

-Gastroesophageal reflux complaints

-Participation

-Quality of Life

-Daily physical activity

Study description

Background summary

In the Netherlands 50-60 newborns with congenital diaphragmatic hernia (CDH) are being born each year. The mortality and morbidity mainly depend on the extent of lung hypoplasia and structural abnormalities of the pulmonary arteries, resulting in persistent pulmonary hypertension of the newborn. Artifiicial ventilation with high pressures and high oxygen concentrations are needed. Long-term pulmonary sequelae include peripheral airway obstruction and increased bronchial responsiveness. Both lung injury due to artificial ventilation and residual lung hypoplasia seem important determinants of persistent lung function abnormalities in CDH patients. Few data are available with respect to exercise endurance in CDH patients. Long-term follow-up in adult CDH patients is limited and restricted to small, cross-sectional studies which include lung function tests but not exercise endurance. More information on lung function abnormalities, exercise endurance, and perception of exercise endurance in young adults with CDH may be beneficial to develop intervention studies at an early stage to prevent complication at the long term, e.g. hypertension, obesity and diabetes.

Study objective

The aim of the present study is to evaluate the long-term pulmonary sequelae, exercise endurance and perception of exercise endurance in adult CDH patients in a cohort that has been studied earlier at a median age of 11.7 years. Lung function results will be compared with earlier data.
Furthermore, the extent of fatigue, quality of life and participation will be evaluated. Data will be compared with data of controls matched for age, gestational age, birth weight, duration of artificial ventilation, duration of supplemental oxygen therapy and sex.

Study design

One part has a longitudinal design (lung function), one part has a cross-sectional design (exercise endurance)

Study burden and risks

The extent of the burden includes a one-day hospital visit. Blood withdrawal will be performed by an experienced physician shortly before and directly after the exercise test. One or two ml of blood will be taken twice; this small amount is not supposed to cause any problems for participants. Venous puncture for blood withdrawal might lead to extravascular bleeding and occurance of a hematoma which may cause a little burden for participants for a short period of time.
In 30 patients who join a pilot study evaluating the daily physical activity during 48 hours the burden includes: carrying a small monitor around the waist

for 48 hours without being able to shower or swim.
Subjects undergoing lung function tests will be asked to stop inhalation of short-acting and long-acting bronchodilators shortly before the tests, according to international standardized guidelines for lung function measurements. A physician will discuss this by phone beforehand, to evaluate whether this can be done without any problems.
Using a standardized questionnaire (PAR-Q) patients will be screened for contraindications to perform maximal exercise tests. In addition a medical history and physical examination will be performed to evaluate safety of maximal exercise performance. In any case of suspicion, subjects will be excluded from this part of the study. During maximal exercise performance a physiotherapist experienced in Basic Life Support is present continuously. All other tests are without risks.

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

congenital diaphragmatic hernia born between 1975 and 1986
participant in cohort studied in 1992-1994
matched controls studied in the same cohort study 1992-1994

Exclusion criteria

refusal to participate
physical or mental disorder leading to inability to perform lung function tests and exercise endurance test adequately
serious comorbidity

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2007
Enrollment:	103
Type:	Actual

Ethics review

Approved WMO

Date:	12-06-2007

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-09-2007
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	NL16520.078.07