Improvement of physical endurance and motor function performance in children with anatomical congenital anomalies and/or following neonatal extracorporeal membrane oxygenation; a randomized study

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The main objective is to improve exercise tolerance. Secondary objectives are: 1) improvement of motor function development, daily physical activity, quality of life, self perception of motor competence, and participation; 2) evaluation of cost...

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

Summary

ID

NL-OMON39643

Source
ToetsingOnline

Brief title
Improvement of physical endurance in pediatric surgical indexdiagnoses

Condition

- Respiratory disorders congenital
- Neonatal respiratory disorders

Synonym
congenital diaphragmatic hernia, esophageal atresia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Kinderrevalidatie Fonds Adriaanstichting

Intervention

Keyword: congenital diaphragmatic hernia, esophageal atresia, extracorporeal membrane oxygenation, physical endurance

Outcome measures

Primary outcome

Change in standard deviation scores on Bruce protocol 3 months after

intervention.

Secondary outcome

-Change in standard deviation scores on Bruce protocol 12 months after

intervention.

-change in motor function development (total impairment score 12 months after

intervention

-change in concentration (Cancellation test) 3 and 12 months after start

intervention

-subjective report on daily physical activity 3 and 12 months after start

intervention

-motor competence selfreport 3 and 12 months after start intervention

-quality of life judged by parents and child 3 and 12 months after start

interventie

-participation 12 months after start intervention

-pro-active coping behaviour of parents 3 and 12 months after start intervention

-evaluation of cost effectiveness

Study description

Background summary

Children with congenital anatomical anomalies and those treated with neonatal ECMO are at risk for decreased exercise tolerance. Early intervention by offering life-style coaching to the child and its family may be beneficial. Addition of an exercise-training program to this intervention may result in further improvement of exercise tolerance. Physical exercise has beneficial effects on concentration in children.

Study objective

The main objective is to improve exercise tolerance. Secondary objectives are: 1) improvement of motor function development, daily physical activity, quality of life, self perception of motor competence, and participation; 2) evaluation of cost effectiveness, 3) evaluation of concentration.

Study design

Single blind, randomized intervention study

Intervention

Group A: lifestyle-coaching for child and it*s family; Group B: lifestyle-coaching for child and it*s family and exercise-training for the child twice a week during 13 weeks; Group C: standard of care, i.e. advise on physical activity (once at outpatient clinic).

Study burden and risks

The burden includes 3 extra hospital visits within 12 months (duration maximal 3 hours, excluding travel time) including a maximal exercise test (each visit; 20 min), evaluation of motor function development (twice: 1 hour) and questionnaires (each visit, approximately 1 hour), concentration task (Cancellation test; 20 min; each visit), flow-volume lung function (once; 30 min).
In Group A and Group B: lifestyle-coaching and change of lifestyle (more physical activity) costs time at home. In Group B extra burden is: exercise

training twice a week during 13 weeks (1 hour; excluding travel time). Risks are not more than expected from regular physical activity at home. Benefits are improvement of exercise tolerance and motor function. From this group of patients we know that they are at risk for decreased exercise tolerance that may deteriorate over time. Therefore, this group may benefit from the intervention.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Children born between 2000 and 2007 with congenital diaphragmatic hernia, esophageal atresia, giant omphalocele and those who have been treated with ECMO in the neonatal period. Inclusion if standard deviation score on the maximal exercise test (Bruce protocol) is

< -1.

Exclusion criteria

- delayed motor function development and need for intervention by a pediatric physical therapist
- inability to perform proper exercise test
- medical contraindication to perform maximal endurance exercise test
- insufficient command of Dutch language to understand instructions

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2012
Enrollment:	99
Type:	Actual

Ethics review

Approved WMO

Date:	06-02-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	19-02-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-04-2014
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	NL38684.078.11