# Improvement of fitness and motor function in children with congenital anomalies.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

## **Summary**

## ID

NL-OMON25080

Source NTR

**Brief title** Beweeg met plezier

#### **Health condition**

congenital anatomical anomalies neonatal ECMO treatment maximal exercise capacity lifestyle coaching exercise training program

congenitale hernia diafragmatica oesofagusatresie ECMO aangeboren kinderchirurgische aandoeningen duuruithoudingsvermogen' motorische ontwikkeling coaching voor het gezin conditietraining

## **Sponsors and support**

**Primary sponsor:** Erasmus MC - Sophia Children's Hospital **Source(s) of monetary or material Support:** Kinderrevalidatiefonds Adriaanstichting Swart van Essen Fonds Dept of Pediatric Surgery, Erasmus MC

## Intervention

## **Outcome measures**

#### **Primary outcome**

Change in standard deviation scores on Bruce protocol 3 and 12 months after intervention.

#### Secondary outcome

- 1. Total impairment score M-ABC test at 12 months;
- 2. Daily activity monitored at 3 and 12 months;
- 3. Questionnaire on daily activity at 3 and 12 months;
- 4. Quality of life at 3 and 12 months;
- 5. Participation at 3 and 12 months;
- 6. Proactive coping competence of parents at 3 and 12 months;
- 7. Cost effectiveness.

# **Study description**

#### **Background summary**

Rationale:

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.

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.

Study design:

Single blind, randomized intervention study.

Study population:

Children born between 2000 and 2006 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.

#### 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).

Main study parameters/endpoints:

Change in standard deviation scores on Bruce protocol 3 and 12 months after intervention.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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

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motor function development (twice: 1 hour) and questionnaires (each visit, approximately 1 hour), flow-volume lung function (once; 30 min). Additionally, an activity monitor is to be worn at home during 7 consecutive days and nights (taken off during shower, swimming classes etc.); 3 times (at start and after 3 and 12 months). This activity monitor is small and won't interfere with regular daily activities.

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.

## **Study objective**

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.

## Study design

3 and 12 months.

#### 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).

Life-style coaching is provided using an online customized program with a page for the child and a page for the parents. A senior physical therapist performs the coaching by establishing a main goal and weekly goals that should be achieved by the child. Duration 13 weeks intensively, followed by 13 weeks less intense if needed.

Exercise-training is performed by a pediatric physical therapist living close to the families' home. The training program is protocollized and will be performed twice a week during 13 weeks.

For standard of care a brochure from our department of pediatric physical therapy will be handed out to the families. This brochure explains how more exercise aiming at improvement of physical endurance can be achieved.

## Contacts

#### Public

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# **Eligibility criteria**

## **Inclusion criteria**

Children born between 2000 and 2006 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**

- 1. (Severely) delayed motor function (i.e. percentilescore < 6 at M-ABC);
- 2. Inability to perform maximal exercise test (Bruce protocol);
- 3. Medical contraindication to perform maximal exercise test;

4. Insufficient command of Dutch language (child or parents) to understand online coaching program.

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# Study design

## Design

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

## Recruitment

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

# **Ethics review**

Positive opinion	
Date:	19-11-2012
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.

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## In other registers

Register	ID
NTR-new	NL3571
NTR-old	NTR3729
Other	METC / KFA : 2011-475 / 2011/0128;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

# **Study results**

Summary results

N/A