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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25080

Bron
NTR

Verkorte titel
Beweeg met plezier

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus MC - Sophia Children's Hospital
Overige ondersteuning: Kinderrevalidatiefonds Adriaanstichting
Swart van Essen Fonds
Dept of Pediatric Surgery, Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 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.

Doel van het onderzoek

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.

Onderzoeksopzet

3 and 12 months.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Dept of Rehabilitation and Physical Therapy
Sophia Children's Hospital
Dr Molewaterplein 60
Monique H.M. Cammen - van Zijp, van der
Rotterdam 3015 GJ
The Netherlands

Wetenschappelijk

Dept of Rehabilitation and Physical Therapy
Sophia Children's Hospital
Dr Molewaterplein 60
Monique H.M. Cammen - van Zijp, van der
Rotterdam 3015 GJ
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2012
Aantal proefpersonen:	99
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	19-11-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A