Exercise Training in Congenital Heart Disease.

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We hypothesize that exercise training will: 1. Improve aerobic fitness; 2. Will not result in adverse remodeling and/or decline of ejection fraction; 3. Will increase daily activity levels; 4. Will improve health related quality of life and…

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

Samenvatting

ID

NL-OMON22464

Bron
Nationaal Trial Register

Verkorte titel
TOFFIT

Aandoening

congenital heart disease - aangeboren hartafwijking
Fontan procedure
Tetralogy of Fallot - Tetralogie van Fallot

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Nederlandse Hartstichting
Stichting Rotterdams Kinderrevalidatie Fonds Adriaanstichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Aerobic fitness;
2. Cardiac functioning;
3. Daily physical activity;
4. Health related quality of life.

Toelichting onderzoek

Achtergrond van het onderzoek

A multi-centered study in the Netherlands to the effect of an exercise training program in children and adolescents (aged 12-20) who have undergone treatment for congenital heart disease (Tetralogy of Fallot and Fontan procedure) on:

1. Aerobic fitness;

2. Cardiac functioning;

3. Daily physical activity;

4. Health related quality of life.

The study has a prospective, randomized, controlled, interventional design.

Doel van het onderzoek

We hypothesize that exercise training will:

1. Improve aerobic fitness;

2. Will not result in adverse remodeling and/or decline of ejection fraction;

3. Will increase daily activity levels;

4. Will improve health related quality of life and psychosocial functioning.

Onderzoeksopzet

Exercise group:

1. Baseline measurements: Within 2 months of the start of the exercise program (T0);

2. Repeated measurements: Within 2 weeks after the completion of the exercise program (T1).

Control group:

Approximately 3 months between baseline measurements and repeated measurements.

Measurements:

1. Aerobic fitness (oxygen uptake and peak power in last half minute of graded bicycle ergometer test);

2. Cardiac functioning (end-systolic and end-diastolic volume of RV and LV (Fallot group) or single ventricle (Fontan group), ejection fraction, functional reserve, NT-proBNP level);

3. Daily physical activity (percentage of day during which dynamic activities have been performed, average motility, assessed by means of an Activity Monitor);

4. Health related quality of life (assessed by TACQOL 12-15 CF and PF, SF-36 and TAAQOL-CHD);

5. Psychosocial functioning (assessed by YSR, ASR, CBCL and ABCL; STAIC, STAI-DY; SPP-A, GSES-12).

Onderzoeksproduct en/of interventie

The patients randomized to the exercise program will perform exercise training. The exercise training program will consist of 3 training sessions of 1 hour per week, for a 3-month period. Training will be aerobic at 60-70% (instead of 60%) of heart rate reserve. Standardized training will be performed group-wise under supervision of a physiotherapist at local fitness-centers. The patients randomized to the control group will continu their daily activities.

A multi-centered study in the Netherlands to the effect of an exercise training program in children and adolescents aged 10-25 instead of aged 12-20.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Surgical repair for Tetralogy of Fallot through transatrial-transpulmonary repair, below the age of 2 years, or;

2. Surgical repair for single ventricle physiology, with intracardiac or extracardiac tunnel, performed before the age of 6 years as a (at least) 2-stage procedure (previous partial cavopulmonary repair);

3. At least 10 years of age;

4. Being followed in Erasmus MC, LUMC, UMC St Radboud, UMCU Wilhelmina Children's Hospital.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Inability to exercise;

2. Mental retardation;

3. Standard contra-indications for MRI;

4. Ventricular outflow obstruction (peak Doppler gradient > 60 mm Hg).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	28-01-2010
Aantal proefpersonen:	150
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	03-02-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37291
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2603
NTR-old	NTR2731
CCMO	NL25800.078.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37291

Resultaten

Samenvatting resultaten
N/A