Exercise Training in Congenital Heart Disease.

No registrations found.

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

Summary

ID

NL-OMON22464

Source
Nationaal Trial Register

Brief title
TOFFIT

Health condition

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

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Nederlandse Hartstichting
Stichting Rotterdams Kinderrevalidatie Fonds Adriaanstichting

Intervention

Outcome measures

Primary outcome

1. Aerobic fitness;

2. Cardiac functioning;

3. Daily physical activity;

4. Health related quality of life.

Secondary outcome

N/A

Study description

Background summary

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.

Study objective

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.

Study design

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).

Intervention

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.

Contacts

Public

Postbus 2060
E.M.W.J. Utens
Rotterdam 3000 CB
The Netherlands
+31 (0)10 7036092
Scientific
Postbus 2060
E.M.W.J. Utens
Rotterdam 3000 CB
The Netherlands
+31 (0)10 7036092

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

1. Inability to exercise;

2. Mental retardation;

3. Standard contra-indications for MRI;

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

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):	28-01-2010
Enrollment:	150
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-02-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37291
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
N/A