Exercise training in congenital heart disease: is it effective and safe and does it improve quality of life

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Objectives:Medical: What is the effect of an exercise training program in children and young adults (up to 20 years of age) who have undergone treatment for ConHD (tetralogy of Fallot or Fontan procedure) on: a) aerobic fitness, b) ventricular size...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Congenital cardiac disorders
Study type	Interventional

Summary

ID

NL-OMON37291

Source
ToetsingOnline

Brief title
Exercisetraining and congenital heart disease

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital

Synonym
congenital heart disease. heart defects

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: congenital, exercise, heart defects, heart failure, quality of life

Outcome measures

Primary outcome

a) measures of aerobic fitness (all patients):

oxygen uptake

peak power in last half minute of graded bicycle ergometer test,

b) measures of cardiac function;

Fallot group: end-systolic right ventricle

end-diastolic volume right ventricle

ejection fraction of right ventricle

end-systolic left ventricle

end-diastolic volume left ventricle

ejection fraction of left ventricle

NT-proBNP level

Fontan group: end-systolic single ventricle

end-diastolic volume single ventricle

ejection fraction of single ventricle

NT-proBNP level

c) measures of daily physical activity:

percentage of day during which dynamic activities have been performed; average

motility

(as assessed by means of an Activity Monitor)

d) health related quality of life, as assessed with questionnaires.

Secondary outcome

None

Study description

Background summary

In children/young adults with congenital heart disease (ConHD), aerobic fitness may be reduced, which may lead to an inactive lifestyle. Poor fitness and an inactive lifestyle have been associated with increased risk of cardiovascular disease and death, and poorer health related quality of life (HRQOL). Exercise training programs may improve fitness and survival, and may reduce ventricular size and neurohormonal activation. Exercise training has improved fitness in small groups of patients with ConHD. Participation in sports activities / exercise training has been recommended. However, information on effectiveness and safety of exercise programs for this population is limited. This is particularly true for lesions with right ventricular (RV) loading abnormalities and/or for single ventricle lesions, in which exercise physiology differs from LV disease states. This has prevented patients from participation in sports. Furthermore, for these reasons adherence to current (Dutch Heart Foundation) exercise training (rehabilitation) guidelines for ConHD patients is poor. For ConHD, patient groups with right ventricular loading abnormalities or single ventricles are important and additional knowledge is required for adequate treatment.
We hypothesize that exercise training will a) improve aerobic fitness, b) will not result in adverse remodeling (increase in ventricular size, neurohormonal activation) and/or decline of ejection fraction, c) will increase daily activity levels and d) will improve HRQOL and psychosocial functioning.

Study objective

Objectives:
Medical: What is the effect of an exercise training program in children and young adults (up to 20 years of age) who have undergone treatment for ConHD (tetralogy of Fallot or Fontan procedure) on: a) aerobic fitness, b) ventricular size, neurohormonal activation, ventricular ejection fraction and c) the level of daily activity
Psychological: 1) What is the effect of an exercise training program in these patients on a) health related quality of life and b) psychosocial functioning.

Study design

In 80 patients with Tetralogy of Fallot and 80 with Fontan circulation (ages 12 - 20 years) 40 patients from each category will be randomized to undergo a 3 months aerobic training program. The others will serve as controls. All patients will undergo detailed cardiological and psychological assessment before and after the 3 month period. This evaluation includes clinical examination, 24 hour ECG, echocardiography, MRI to assess ventricular volumes and ejection fraction, graded exercise testing with assessment of oxygen uptake and work load, 48-hour activity monitoring (accelerometry-based), blood N Terminal-pro Brain Natriuretic Peptide level, and standardized questionnaires and semi-structured interview to assess HRQOL.

Intervention

Exercisetraining, 3 times a week, for 1 hour /training, aerobic level (target heart rate 60 % of maximal heartrate during exercise), for a 3 month period.

Study burden and risks

All clinical examinations are the same as are routinely performed during follow-up of patients operated for tetralogy of Fallot or those who have undergone the Fontan procedure, including dobutamine stress MRI.
For the purpose of the research proposal examinations will be clustered (T0 assessment), and will be repeated after 3 months (T1 assessment). Standardized questionnaires and semi-structured interview to assess HRQOL are only performed for research purposes.
A standard history, physical examination and ECG are performed. The patient is subjected to an exercise test. After a 30 min. rest blood is drawn. Cardiac MRI is performed. psychological examination is performed by means of standardized questionnaires and a semi-structured interview. At the end of the visit instructions on the 24-hour ECG and activity-monitor will be given. All examinations will be performed at the same day, unless the patient prefers otherwise. The total duration of these examinations is 5 hours.
Half of the patients will also perform aerobic exercise training at submaximal level for 3 months. This is training of moderate intensity level. In small comparable patient groups, no adverse effects have been reported. Positive effects (increase in exercise performance, activuty level) have been reported.
All research results will be coded in a source document and will be stored in a database. Bodily fluids will be given the same code. Of each participant 2 X 500 microliter blood will be kept for possible future use.
Burden and risk are similar to those of regular clinical procedures and follow-up.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2060
3000 CB Rotterdam
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2060
3000 CB Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- Surgical repair for Tetralogy of Fallot through transatrial-transpulmonary repair, below the age of 2 years, or
- 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),
- Age at inclusion at least 10 years of age,
- Being followed in Erasmus MC, LUMC, UMC St Radboud, UMCU Wilhelmina Children*s Hospital,

Exclusion criteria

- Inability to exercise
- Mental retardation
- Standard contra-indications for MRI
- Ventricular outflow obstruction (peak Doppler gradient > 60 mm Hg)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-01-2010
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	14-04-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-02-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	18-10-2011
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

ID: 22464
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL25800.078.09
OMON	NL-OMON22464