The Effect of Exercise Training in Adult Patients with a Systemic Right Ventricle; Three Year Follow-Up

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Observational invasive

Summary

ID

NL-OMON37215

Source
ToetsingOnline

Brief title
Exercise and TGA

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital
- Lifestyle issues

Synonym
congenital heart disease, traonsposition of the great vessels

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Netherlands Heart Institute (ICIN)

Intervention

Keyword: Adult Congenital Heart Disease, Exercise, Transposition of the Great Arteries

Outcome measures

Primary outcome

Maximal exercise capacity measured by cardiopulmonary exercise testing.

Secondary outcome

Health related quality of life

Serum NT-proBNP

Current exercise habits

Clinical events

Study description

Background summary

The American Heart Association recommends patients with acquired heart disease to participate in exercise training. Exercise training improves exercise capacity and quality of life in these patients, and it also decreases morbidity and mortality. Recently, we demonstrated that exercise training is also beneficial in patients with a systemic right ventricle due to a surgically corrected transposition of the great arteries (TGA) or a congenitally corrected transposition of the great arteries (ccTGA). In this study, performed in 2009, a ten week home based step aerobic exercise program increased maximal exercise capacity.

However, it remains unclear whether this was only a temporary effect for the duration of the exercise program, or whether exercise training also exerted a long term effect. Moreover, engaging in habitual exercise in research setting might have prompted participants to engage in sport or increase their exercise frequency. Finally, as exercise training decreases mortality and morbidity in patients with acquired heart disease, this might also be the case in patients with a systemic right ventricle.

Study objective

The primary objective of the study is to determine whether exercise training exerts a long term effect on maximal exercise capacity, clinical events, sports participation, serum NT-proBNP and quality of life in adults with a systemic right ventricle due to a surgically or congenitally corrected TGA.

Study design

Three year follow-up of randomized controlled trial. Single crosssectional re-evaluation of all participants

Study burden and risks

Patients are requested for a one-time visit to the hospital for additional follow-up examinations. These include a cariopulmonary exercise test, two questionnaires, an interview concerning their current exercise habits and venapunction.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with a systemic right ventricle due to a congenitally or atrially corrected traonsposition of the great arteries, who participated in the 2009 exercise trial.

Exclusion criteria

- Cardiac and/or non-cardiac co-morbidity that may jeopardize patient safety during cardiopulmonary exercise testing.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2013
Enrollment:	39
Type:	Actual

Ethics review

Approved WMO Date:	11-01-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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.

In other registers

Register	ID
CCMO	NL41508.018.12