The Effect of Exercise Training in Adult Patients with a Systemic Right Ventricle.

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

Samenvatting

ID

NL-OMON21401

Bron
NTR

Verkorte titel
N/A

Aandoening

transposition of the great vessels
systemic right ventricle

Ondersteuning

Primaire sponsor: Academic Medical Center
Overige ondersteuning: Inter University Cariology Institute of the Netherlands (ICIN)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of the study is to determine whether exercise training improves

maximal exercise capacity in adult patients with a systemic right ventricle due to an atrially switched TGA, or to a ccTGA.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
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. Despite these improvements seen with exercise training in patients with acquired heart disease, available data on the effect of exercise in adult patients with a congenital heart defect are limited. However, the prevalence of adult patients with a congenital heart defect has increased steadily over the last decades. A substantial portion of these patients has a morphologic RV supporting the systemic circulation (e.g. patients with congenitally corrected transposition of the great arteries (ccTGA) and patients with complete transposition of the great arteries (TGA) after an atrial switch operation). Complications are frequent and long-term survival is comprised in most of these patients. Currently, a large number of patients with a systemic right ventricle lead a sedentary lifestyle caused by overprotection by their parents and physicians. Moreover, lack of available literature on exercise in these patients has lead to restrictive European recommendations on exercise and sports participation. The reticence could have unintentional counterproductive effects. In children with congenital heart defects physical training has a proven beneficial effect, both on exercise capacity and on a psychosocial level. These results could well be applicable to adult patients with a systemic RV.

Objective:
The objective of the present study is to evaluate the effect of exercise training on exercise capacity, serum NT-proBNP levels and quality of life in adult patients with a systemic right ventricle.

Study design:
multi-centre, prospective, randomised trial with blinded evaluation of patient outcomes. Follow-up ten weeks.

Study population:
All adult patients with a systemic right ventricle are potentially eligible for this study.

Intervention:
one group participates in a home-based exercise program for the duration of ten weeks. One group does not undergo intervention.

Main study parameter:
the main study parameter is the change in VO2max as determined by cardiopulmonary exercise test.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
all investigations, blood analysis excepted, are non-invasive and free of risk. The burden for the patients mainly consists of the time that is consumed by the investigations, namely: history taking + physical examination (15 min); Quality-of-Life questionnaire (15 min); laboratory tests (2 times 12 ml); EKG (10 min); cardiopulmonary exercise test (1 hour). Risks from the exercise training program are limited.

Doel van het onderzoek

We hypothesize that exercise training improves maximal exercise capacity in adult patients with a systemic RV. Moreover, we hypothesize that exercise training decreases serum NT-proBNP levels and increases quality of life in adult patients with a systemic RV.

Onderzoeksopzet

1. 1-3 months: patient identification & recruitment;

2. 3-6 months: baseline investigations & participation exercise program;

3. 6-9 months: close-out visits;

4. 9-12 months: data analysis & report writing.

This is an international multi-centre trial, which involves extensive logistical organisation of the trial. Therefore, we allow for a 3 month extension of the trial.

Onderzoeksproduct en/of interventie

Eligible patients are randomly assigned to:

1. Exercise training program;

2. No exercise training program.

The training program is commenced directly after the cardiopulmonary exercise test, with the first exercise scheduled two days after the cardiopulmonary exercise test. Patients are requested to perform an interval exercise training at home, climbing stairs, three times a week for 10 consecutive weeks. The training schedule is set-up as follows:

1. 5 minutes of warming-up to reach 60-70% of maximal heart rate;

2. 30 minutes of interval exercise training (stair climbing). The interval training consists of five 4-minute intervals at 90-95% of maximal heart rate, as previously determined by the cardiovascular exercise test. These intervals are separated by 2-minute pauses, stepping in place at 50-70% of maximal heart rate;

3. 5 minutes of cool-down at 50-70% of maximal heart rate.

Total exercise time is 40 minutes per exercise.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

All adult (18 years old, or older) patients with an atrially switched TGA or with a ccTGA (i.e. a systemic right ventricle) are potentially eligible for this study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Mental or physical incapability to give informed consent;

2. Mental or physical incapability to participate in the exercise training program;

3. Exercise-induced arrhythmias;

4. Symptomatic myocardial ischemia;

5. Resting systolic blood pressure > 200 mmHg and/or diastolic blood pressure > 110 mmHg;

6. NYHA class III or IV;

7. Severe aortic valve stenosis;

8. Pregnancy (during training period);

9. Permanent pacemaker in situ;

10. Non-cardiac co-morbidity that may affect exercise performance or that may aggravate by exercise (e.g. infection, renal failure).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2009
Aantal proefpersonen:	95
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-01-2009
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	NL1561
NTR-old	NTR1641
Ander register	MEC AMC : 08/321
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A