Exercise in patients with a systemic right ventricle.

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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...

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

Samenvatting

ID

NL-OMON26970

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Patients with a transposition of the great arteries who have undergone a Mustard or Senning correction in the past, and patients with a congenitally corrected transposition of the great arteries.

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Overige ondersteuning: Interuniversity Cardiology Institute of the Netherlands

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

Netherlands (Amsterdam, Nijmegen, Groningen)

Italy (Bologna)

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

Baseline and after 10 weeks of follow-up.

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. To enhance willingness to participate the training schedule is home-based. 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. 32 minutes of interval exercise training (stair climbing / aerobic steps). 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 3-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 42 minutes per exercise.

Patients can follow their heart rate during the exercise training with the Cresta Metal Line PM-233 heart rate wrist watch, which will be provided to them directly after randomization.

To improve compliance, consenting patients can choose their exercise training – stair climbing or steps aerobics (patients choosing steps aerobics will be provided with a steps). Moreover, to improve compliance and to ensure safety of the exercise training, each patients will be telephoned weekly during the course of their program.

Contactpersonen

Publiek

Academic Medical Centre (AMC)
Department of cardiology
Room F3 – 115
B.J.M. Mulder
Meibergdreef 9
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5666051

Wetenschappelijk

Academic Medical Centre (AMC)
Department of cardiology
Room F3 – 115
B.J.M. Mulder
Meibergdreef 9
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5666051

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)

Patients are not eligible for this study if the following exclusion criteria apply:

1. Mental or physical incapability to give informed consent;

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

3. Symptomatic myocardial ischemia;

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

5. NYHA class III or IV;

6. Severe aortic valve stenosis;

7. Pregnancy (during training period);

8. 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:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2009
Aantal proefpersonen:	86
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-07-2009
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	NL1799
NTR-old	NTR1909
Ander register	MEC Academic Medical Center Amsterdam : 08/342
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A