Exercise in patients with a systemic right ventricle.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26970

Source
Nationaal Trial Register

Brief title
N/A

Health condition

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.

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Source(s) of monetary or material Support: Interuniversity Cardiology Institute of the Netherlands

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

The secondary objectives of the study are to determine whether exercise training:

1. Decreases serum NT-proBNP levels;

2. Improves health related quality of life in adult patients with a systemic right ventricle.

Study description

Background summary

Netherlands (Amsterdam, Nijmegen, Groningen)

Italy (Bologna)

Study objective

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.

Study design

Baseline and after 10 weeks of follow-up.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2009
Enrollment:	86
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-07-2009
Application type:	First submission

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
NTR-new	NL1799
NTR-old	NTR1909
Other	MEC Academic Medical Center Amsterdam : 08/342
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A