High intensity interval training in patients with tetralogy of Fallot

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Primary Objective: To examine the effect of an online based exercise training protocol on ventriculo-arterial coupling , as assessed by pulse wave velocity and wave reflection patterns in the aorta and pulmonary artery in patients operated for...

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

Summary

ID

NL-OMON51183

Source
ToetsingOnline

Brief title
TOFHIIT study

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital

Synonym
Tetralogy of Fallot

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cardiac MRI, Congenital heart disease, high intensity interval training

Outcome measures

Primary outcome

Decrease in pulse wave velocity in the aorta and pulmonary artery measured by MRI.

Secondary outcome

1. Exercise capacity measured with a cardiopulmonary exercise test (VO2 peak and Wattage peak)

2. Other measures of cardiac function:

• MRI: Left and right end diastolic, end systolic, stroke volume and ejection fraction. Changes in wave reflection patterns in the pulmonary artery as measure by Schafer et al. (1) Mass and thickness of the ventricle wall. Flow variables in the aorta and pulmonary arteries not covered by our main endpoint including 4D flow analysis.

Patient data can be compared to existing local reference data of healthy volunteers

• Echo: Two-dimensional echocardiography An echocardiogram will be made by a trained sonographer or pediatric cardiologist. Oon a commercially available ultrasound platform. Echocardiography Wwill be used to assess the following variables of cardiac size and function: Global ventricular function (ventricular volumes, ejection fraction)

Regional ventricular function: right and/or left ventricular or single ventricular global and regional strain / strain rate. Diastolic ventricular

function: peak velocity of the antegrade systolic wave, early diastolic wave and the peak velocity of the late diastolic retrograde wave will be measured of the pulmonary venous flow E and A velocities, and E - A ratio will be assessed of systemic atrioventricular flows. Semiquantitative assessment of semilunar and atriovernricular valve regurgitation. Patient data can be compared to existing local reference data of healthy volunteers.

3. Changes in body fat percentage, height and weight and their derivates BMI and BSA

4. Questionnaires of QoL

• Will be assed using CHQ-PF28, CHQ-CF45, SF36 (for persons above 18) and SQUASH)

Study description

Background summary

Tetralogy of Fallot is the most common type of cyanotic congenital heart disease. The main problems of this patient population are heart failure related to chronic pulmonary regurgitation, arrhythmias and sudden cardiac death. A major gap in our knowledge is how coupling between the RV and pulmonary artery affects outcomes. A promising method to investigate RV-PA coupling is by looking at pulse wave velocity and wave reflection patterns in the main pulmonary artery and proximal branches non-invasively. It has been shown that left sided pulse wave velocity can be improved by exercise training in Tetralogy of Fallot by exercise training.

Study objective

Primary Objective: To examine the effect of an online based exercise training protocol on ventriculo-arterial coupling , as assessed by pulse wave velocity and wave reflection patterns in the aorta and pulmonary artery in patients operated for Tetralogy of Fallot.

Study design

The design of our study is a cross-over interventional study. All children and young adults will be randomized in 2 groups. One group will start with care/exercise as usual, the other group will start with an online exercise training. After 12 weeks the groups will change from protocol. Before start of measurements, after 12 weeks and group 2 after 24 weeks, all participants will undergo a number of tests, including echocardiogram, cardiopulmonary exercise test, and cardiac magnetic resonance imaging.

Intervention

12 weeks of online based interval training 3 times a week.

Study burden and risks

Children and young adults who will be included in the study have no restrictions in their level of physical exercise. In daily life they are subject to peak physical exercise levels. In previous projects (METC 2006-310, 2009-033, 2009-134, 2014-326) in similar patients we have not encountered any untoward effects in exercise testing, nor in exercise training (METC 2009-134).

The effects of exercise training will be evaluated. Exercise training in similar patients has been performed without serious adverse effects. (2-4) We therefore do not expect an increased risk for the patients. Furthermore, these patients will have had detailed evaluation, including exercise testing, MRI and echocardiography before they enter into exercise training. The burden of the study procedures is limited. Procedures are those routinely performed during regular follow-up in these patient categories, and are not harmful. Exercise training is a recommended part of standard care during follow-up after repair of tetralogy of Fallot. In earlier, similar studies in children with congenital heart disease we did not encounter or notice any untoward effects of imaging procedures or exercise testing. (2, 5, 6) Heart rhythm disturbances have been reported to occur during exercise testing. In previous studies no (severe) adverse effects of exercise training have been reported in patients with congenital heart disease.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

• Surgical repair for Tetralogy of Fallot through transatrial-transpulmonary repair, below the age of 2 years.
• Between 12 and 30 years of age
• Being followed in ACAHA (academisch centrum voor aangeboren hartafwijkingen, Erasmus MC, Sophia Childers hospital, Radboud UMC, Amalia children*s hospital)
• Does not comply with the *Nederlandse Norm Gezond Bewegen*

Exclusion criteria

• Inability to exercise or a contraindication for exercise such as long QT syndrome
• Ventricular outflow obstruction (gradient of over 36 mmHg)
• Developmental delay
• Standard contra-indications for MRI
• Use of beta blockers
• Documented cardiac arrhytmias

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	14-01-2022
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO Date:	24-08-2021
Application type:	First submission
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: 29511
Source: NTR

Title:

In other registers

Register	ID
CCMO	NL76553.078.21