High intensity interval training in patients with tetralogy of Fallot

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HIIT can lower PWV in the Aorta and pulmonary Artery in patients with Tetralogy of Fallot

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

Samenvatting

ID

NL-OMON29511

Bron
NTR

Verkorte titel
TOFHIIT

Aandoening

Tetralogy of Fallot

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Nederlandse Hartstichting & Stichting Hartekind

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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.
Objective: Primary Objective: To examine the effect of an online based exercise training protocol on ventriculo-arterial coupling , as assessed by pulse wave velocity in the aorta and pulmonary artery in patients operated for Tetralogy of Fallot.
Secondary Objective(s): To examine the effect of an online based exercise training protocol on the increase in exercise capacity and quality of life in patients with 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.
Study population: 12-30 years of age, after surgical repair of tetralogy of Fallot (TOF), being followed at one of the 2 locations of the Academic Center for Congenital Heart disease (ACAHA) (Erasmus MC, Sophia children’s hospital, Radboud UMC Amalia children’s hospital).
Intervention (if applicable): 12 weeks of online based interval training 3 times a week.
Main study parameters/endpoints: Decrease in pulse wave velocity in the aorta and pulmonary artery measured by MRI.

Doel van het onderzoek

HIIT can lower PWV in the Aorta and pulmonary Artery in patients with Tetralogy of Fallot

Onderzoeksopzet

Group A
Baseline (week 0)
After excercise program (week 12)

Group B
Baseline (week 0)
After control period (week 12)
After excercise program (week 24)

Onderzoeksproduct en/of interventie

Trainings intervention:
Due to the ongoing COVID-19 pandemic we prefer an online intervention (example shown at: https://pedcardio.shinyapps.io/TOFHIIT-example/), in this pandemic it is not clear if/when gyms and physiotherapists will be available.One training a week consists of jump roping (training 1), one training are body weight exercises (training 2) and the last training is one of the choosing of the participants such as running or bike riding (training 3). All trainings are approximately 30 minutes in length Training 1 and 2 will be monitored in a MS teams session and via heart rate monitor (HRM), training 3 can be done at a time of the choosing of the participant and the heart rate monitoring file will be sent to the researcher. Training 1 and 3 will be done using the 10-20-30 HIIT protocol which has been shown to be more effective compared to continues moderate intensity training. This protocol can be used in different activities in short it consists of 10 seconds of high intensity followed by 20 seconds of moderate intensity followed by 30 seconds of very light intensity.

Contactpersonen

Publiek

Erasmus MC
Wouter van Genuchten

0031 10 7040823

Wetenschappelijk

Erasmus MC
Wouter van Genuchten

0031 10 7040823

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

* 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 Erasmus MC, Sophia Childers hospital, Radboud UMC, Amalia children’s hospital
* Does not comply with the “Nederlandse Norm Gezond Bewegen”

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

* Inability to exercise or a contraindication for exercise such as long QT syndrome
* Contra indication for MRI such as a non MRI compatible pacemaker
* Ventricular outflow obstruction higher than 36 mmHg
* Developmental delay
* History of pulmonary valve replacement
* Use of beta blockers
* Documented cardiac arrhytmias

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2021
Aantal proefpersonen:	44
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	27-09-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 51183
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9754
CCMO	NL76553.078.21
OMON	NL-OMON51183

Resultaten