Exercise capacity in Tetralogy of Fallot: heart, lungs or muscles?

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Primary Objective(s): - To determine the relation between CPET and pulmonary and muscular performance in patients with Tetralogy of Fallot.- To study the effect of previous lateral thoracotomy on pulmonary function and exercise.Secondary Objective(s...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Observational non invasive

Summary

ID

NL-OMON42647

Source
ToetsingOnline

Brief title
Exercise capacity in Tetralogy of Fallot

Condition

- Congenital cardiac disorders
- Cardiac and vascular disorders congenital

Synonym
congenital heart defect, Tetralogy of Fallot

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Exercise capacity, Muscle strength, Pulmonary function, Tetralogy of Fallot

Outcome measures

Primary outcome

Main endpoint: Cardiopulmonary exercise testing (peak VO2).

Main study parameters:

1. Cardiac function (EF on MRI)

2. Pulmonary function (FVC)

3. Muscle strength (BOT-2)

Secondary outcome

1. CPET variables: peak workload, peak Ve, Ve/VCO2 slope, O2-pulse, heart rate response to exercise (28).

2. Cardiac assessment: residual lesions on echo (valve insufficiency and/or stenosis) graded according to Hamer and Pieper. Ventricular morphology and volumes on MRI (29)

3. Pulmonary function: total lung capacity (TLC), force expiratory volume in 1 second (FEV1), maximal inspiratory/expiratory pressures (MIP/MEP), residual volume (16,17).

4. Muscle strength: handgrip strength, isotonic muscle strength (hand-held dynamometer of quadriceps, triceps and biceps).

5. Quality of life assessed with PedsQL.

6. Physical activity measured with accelerometer.

Study description

Background summary

Tetralogy of Fallot (ToF) is the most prevalent form of cyanotic congenital heart disease (ConHD), affecting the right ventricle and pulmonary arteries. Although mortality is low, morbidity (caused by inevitable residual lesions after surgery) is increasing threatening the Quality of Life (QoL) of the patient. Surgical strategies have evolved in time, aimed to reduce the effect of prolonged right ventricular overload. However, it is yet unknown if these changes, indeed reduce the risk of attrition. Studies in children and young adults with ToF in the literature are scarce.
The golden standard to monitor the cardiac function in ToF patients is to perform a cardiopulmonary exercise test (CPET), with primary outcome peak oxygen uptake (peak VO2). The CPET is not only an indicator for cardiac function, but also for pulmonary function and muscle strength. Previous studies demonstrated a decreased peak VO2 in young patients with ToF. Whether this is related to cardiac function is doubtful. Patients with ConHD have a higher prevalence of restrictive lung patterns and respiratory and skeletal muscle weakness. Also, patients with ConHD tend to be less physically active than their peers. In our preliminary study, we studied 28 ToF patients and 11 healthy controls, are results were similar to findings in the literature. Additionally, patients with a previous Blalock-Taussig shunt (BT-shunt) showed a disadvantage compared to primary repaired ToF patients. Therefore we hypothesize: 1. Reduced pulmonary function and reduced muscular strength, rather than cardiac function, have a negative effect on CPET outcome (peak VO2). 2. Previous lateral thoracotomy has a negative effect on the CPET outcome (peak VO2) due to a poorer pulmonary function. 3. QoL correlates with clinical status cardiac function, pulmonary function and muscle strength. 4. Physical inactivity has a negative effect on CPET (peak VO2) results due to lower muscle strength.

Study objective

Primary Objective(s):
- To determine the relation between CPET and pulmonary and muscular performance in patients with Tetralogy of Fallot.
- To study the effect of previous lateral thoracotomy on pulmonary function and exercise.

Secondary Objective(s):
- To determine pulmonary function and muscle strength in children and adolescents after early ToF-repair.
- To assess the relationship between clinical parameters (heart, lung, muscle) with QoL of children and adolescents after ToF-repair.

- To determine predictors of a decreased peak VO2.
- To study the physical activity in relation to exercise performance and muscle strength.

Study design

Observational cross-sectional study (period end-2015 until mid-2019).

Study burden and risks

Benefits for patients and controls
The study leads to a detailed analysis of the physical performance of the participant. This analysis will be shared with the participants and their parents/legal representatives. Participants and parents/legal representatives can receive a personal patient-tailored advice to improve their physical status based upon these results.

The burden for patients and controls is a longer stay in the hospital of additionally 1.5 respectively 2 hours. Also, during the pulmonary function test an unknown obstructive lung pattern may be revealed. Additional examinations and treatment will be started if necessary. The control group will undergo the CPET instead of an ergometry. Ergometry is easier and without a face mask. The burden for the muscle examinations, accelerometer and general QoL questionnaire are low.

Risk assessment for both groups: All examinations to be carried out in this study are part of routine follow-up care in other pediatric patient groups (e.g. pulmonary function in asthma and cystic fibrosis, muscle strength tests in muscle dystrophy). Pulmonary function testing and muscle strength assessment are without risks. Complications that may occur during a CPET are chest pain (0.69%), dizziness or syncope (0.29%), decreased blood pressure (0.35%) and hazardous arrhythmias (0.46%). The overall incidence of complications during pediatric exercise testing is 1,79% (Alpert et al). However 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 exercise levels, without any type of monitoring.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB

NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

1) Children and adolescents corrected for Tetralogy of Fallot, 21 years old or younger (minimum age of 8) followed routinely in the University Medical Centre Groningen.
2) Children and adolescents with a corrected Coarctatio aortae, 21 years old or younger (minimum age of 8) followed routinely in the University Medical Centre Groningen.
3) Height > 120 cm in order to be able to fit on the bicycle.
4) Written informed consent.

Exclusion criteria

For all participants
- Patients with mental retardation.
- Patients who have contra-indications for exercise testing.
- Patients known with a muscular dystrophy (such as Becker or Duchenne).
- Patients with instable lung disease.
- Patients with previous surgery for scoliosis.
- Pregnant patients;For patients with coarctatio aortae

- Patients with more than one surgical intervention.
- Patients known to suffer from a hemodynamic significant re-coarctation (definition: pressure differences between ascending and descending aorta > 20 mmHg).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-03-2016
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	02-12-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL53571.042.15