Reassessing patients with repaired tetralogy of Fallot and severe pulmOnary Regurgitation using Cardiac Exercise hemodynamics

Published: 09-04-2025
Last updated: 28-04-2025

To study the feasibility of invasive exercise right heart catheterization in adult patients with repaired tetralogy of Fallot and severe PR and to study exercise parameters in volume loaded RV in repaired tetralogy of Fallot which could help to...

Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac valve disorders
Study type	Observational invasive

Summary

ID

NL-OMON57416

Source
ToetsingOnline

Brief title
R-FORCE I

Condition

- Cardiac valve disorders
- Cardiac and vascular disorders congenital

Synonym
Pulmonary regurgitation, pulmonary valve leakage

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: Invasive exercise hemodynamics, Severe Pulmonary regurgitation, Tetralogy of Fallot

Outcome measures

Primary outcome

Difference in cardiac index at peak exercise between patients with an

indication for PVR versus patients without an indication.

Secondary outcome

1. The safety of invasive exercise right heart catheterization in this specific

population by quantifying the amount of procedure-related (serious) adverse

events.

2. Difference between PCWP, mean RAP and RAP/PCWP ratio at peak exercise

between patients with and without an indication for PVR.

3. PCWP at peak exercise; cardiac index at peak exercise; mean pulmonary artery

pressure at peak exercise; mean RAP at peak exercise; RAP/PCWP ratio at peak

exercise; PCWP minus RAP at peak exercise; RV stroke work index at peak

exercise.

4. All these individual parameters at rest and at 20 Watt exercise.

5. Change in all the individual parameters objective from rest to peak exercise.

6. Peak work load achieved in Watts.

Study description

Background summary

Many adult patients with a repaired tetralogy of Fallot have severe, residual pulmonary regurgitation (PR) requiring a pulmonary valve replacement (PVR) later in life. PVR is recommended in patients with symptoms that are unequivocally due to severe PR. In asymptomatic patients however, PVR should also be considered when severe PR is seen in combination with e.g. a decrease in objective exercise capacity, progressive right ventricular (RV) dilatation, progressive tricuspid regurgitation, progressive RV systolic dysfunction, and/or a wide QRS duration on electrocardiography. However, the optimal timing of PVR in this specific group of patients with severe, residual PR remains challenging, especially in asymptomatic patients. This clinical dilemma has also been acknowledged in the most recent Guidelines on Adult Congenital Heart Disease as an important gap in evidence. Except for cardiopulmonary exercise testing (CPET), most parameters that guide the decision on timing of PVR are obtained at resting conditions. Yet, patients typically complain of symptoms during exercise and very often a dissociation is seen between reported symptoms and only minor functional and/or morphological abnormalities on resting cardiac imaging. We hypothesize that invasive hemodynamic exercise testing may unmask important hemodynamic abnormalities caused by severe PR and RV volume overload. Hemodynamic perturbations revealed with exercise may help in the understanding of the consequences of severe, longstanding PR and may guide further studies that aim to optimize the timing of PVR, especially in the difficult group of *asymptomatic* patients.

Study objective

To study the feasibility of invasive exercise right heart catheterization in adult patients with repaired tetralogy of Fallot and severe PR and to study exercise parameters in volume loaded RV in repaired tetralogy of Fallot which could help to improve the timing of PVR.

Study design

Feasibility/pilot study.

Study burden and risks

Right heart catheterization in an experienced centre is associated with a low risk of minor and major complications. The risk of complications related to venous access (e.g. hematoma, vagal reactions and pneumothoraxes) was, all together, <1.0%. The risk of complications directly related to right heart catheterization (e.g. arrhythmia, hypotensive episodes, transient ischemic

attack) was, all together, 0.003%. The risk of mortality was 0.055%). Patients need to be hospitalized at the day of the procedure and need to undergo an invasive right heart catheterization requiring venous access via the internal jugular vein while performing a bicycle exercise test in supine position, which will take approximately 30-60 minutes whereby the patient will be in the HC room for a totalduration of approximately 1-2 hours.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Age 18 years or older
2. Repaired tetralogy of Fallot with or without a transannular patch.
3. Severe PR.
4. Ability to perform a supine bicycle exercise test.

5. Willingness to sign informed consent

Exclusion criteria

1. More than moderate tricuspid regurgitation.
2. Significant residual shunt (e.g. residual aorto-pulmonary shunt, ventricular septal defect or arteriovenous shunts).
3. Moderate or severe RV outflow tract obstruction or known pulmonary artery stenosis.
4. Inability to perform a supine bicycle exercise test.
5. Pregnancy. Women of childbearing age must provide a negative pregnancy test.
6. Mechanical valvular prosthesis in the pulmonary or tricuspid valve position.
7. Pulmonary embolism.
8. Pulmonary arterial hypertension with pulmonary vascular resistance >=3 Wood units
9. Uncontrolled arrhythmia with resting heart rate >110 bpm.
10. Decompensated heart failure.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2025
Enrollment:	22
Type:	Anticipated

Ethics review

Approved WMO

Date:	09-04-2025
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	NL87508.042.24