Evaluation of the clinical impact of ventricular dyssynchrony in patients with corrected tetralogy of fallot

No registrations found.

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

Summary

ID

NL-OMON23806

Source
NTR

Brief title
N/A

Health condition

Tetralogy of Fallot (tetralogie van Fallot), pulomnary valve replacement (pulmonaalklepvervanging) ventricular dyssynchrony (ventrikel dyssynchronie)

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: "Willem Alexander Kinder en Jeugd fonds"

Intervention

Outcome measures

Primary outcome

Primary outcome: Differences in time to peak systolic velocity between different segments of the right ventricle:

- Right ventricular outflow tract

- Right ventricular free wall

- Right ventricular septum.

The greatest difference in time to peak systolic velocity of the segments (latest peak systolic velocity minus earliest peak systolic velocity) will be used as a measure of dyssynchrony, and this value will be compared before and after PVR

Secondary outcome

Effect of PVR on ventricular function
(eg. volume, diastolic function, E/A ratio, pulmonary regurgitation, Vo2 max, clinical condition)

Study description

Background summary

Prospective study to evaluate the effect of pulmonary valve replacement on mechanical ventricular dyssynchrony in young corrected tetralogy of Fallot patients

Study objective

Improvement of the RV function by pulmonary valve replacement will result in improvement of RV dyssynchrony in corrected tetralogy of Fallot patients

Study design

- approximately 3-6 months before PVR

- approximately 3-6 months after PVR

Intervention

Group: patients with corrected Tetralogy of Fallot who undergo pulmonary valve replacement.

Intervention: pulmonary valve replacement (PVR), surgical or percutaneous

Contacts

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Eligibility criteria

Inclusion criteria

1. Corrected tetralogy of fallot

2. >8 year

3. Scheduled for pulmonary valve replacement

Exclusion criteria

1. Claustrophobia

2. Renal disease

3. Cardiac arrythmia

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-07-2008
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-07-2008
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	NL1329
NTR-old	NTR1388
Other	METC LUMC : p08.023
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A