COmprehensiVE assessment of peRcutaneous implanted pulmonary valve prostheses to determine the incidence of *HALT*. An exploratory study.

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Primary: Determine the incidence of HALT after PPVI on CT. Secondary: Relate the occurrence of HALT to blood biomarkers and flow profiles on MRI. Determine the ability to detect HALT by TTE in patients that underwent PPVI

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON54990

Source
ToetsingOnline

Brief title
COVER study

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
PPVI endocarditis; infection of endocardium/heart valves

Research involving
Human

Sponsors and support

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

Intervention

Keyword: CT, MRI, Prosthetic heart valve

Outcome measures

Primary outcome

Incidence of HALT as detected by computed tomography CT on percutaneously

implanted pulmonary prosthetic heart valves.

Secondary outcome

Secondary, the relation of blood biomarkers and MRI flow profiles to HALT.

Incidence of HALT on TTE.

Study description

Background summary

Percutaneous pulmonary valve implantation (PPVI) is an effective procedure in patients with congenital heart diseases involving the right ventricular outflow tract (RVOT). Concerns have been raised about the incidence of PPVI endocarditis that may be related to thrombus formation on the valve. Recently, reports have emerged describing the occurrence of hypo-attenuating leaflet thickening (HALT) on other transcatheter valves. It*s unknown if HALT also occurs after PPVI and whether it is related to endocarditis. Furthermore, little is known about the CT and MRI findings after PPVI.

Study objective

Primary: Determine the incidence of HALT after PPVI on CT.
Secondary: Relate the occurrence of HALT to blood biomarkers and flow profiles on MRI. Determine the ability to detect HALT by TTE in patients that underwent PPVI

Study design

Exploratory cross-sectional observational study.

Study burden and risks

As part of the study patients undergo a cardiac CT scan. Patients also undergo a transthoracic echocardiogram (TTE), blood samples and an MRI scan which are all part of the routine clinical care. Tests are planned to be performed on the same day during a regular visit to the outpatient clinic.
For the cardiac CT scan the patient is exposed to ionizing radiation which carries a small risk of future induced neoplasms. Furthermore, iodinated contrast material is injected which carries a small risk of an allergic reaction.
Blood samples are taken for which a venous puncture is needed. This carries a negligible risk. The MRI scan is considered safe. Gadolinium based contrast agent is administrated which carries a small risk of an allergic reaction.
The benefit for the patient may lie in the fact that a comprehensive analysis of their prosthetic heart valve and heart is performed. Patients that underwent PPVI remain under lifelong follow-up by a cardiologist; almost all have a congenital heart defect and are likely to need to undergo additional invasive or surgical procedures in the future. The information gained from this study may aid planning future interventions.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Underwent PPVI
- Age > 18 years

Exclusion criteria

- Pregnancy
- Unwillingness to sign informed consent
- Known allergy to iodinated contrast material
- Indication to perform prehydration prior to intravenous contrast material admin-istration according to the guidelines in the EMC
- Unwillingness to be informed about unrequested findings on the CT

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-09-2020
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	30-07-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-04-2021
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL71294.078.19