Clinical outpatient control after valve-sparing hartoperation

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

Summary

ID

NL-OMON40813

Source
ToetsingOnline

Brief title
TironDavid Onderzoek

Condition

- Cardiac valve disorders
- Cardiac therapeutic procedures

Synonym
VSARR / valve sparing aortic vessel operation

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: Open hart surgery, Reimplantation, Tiron David, Valve sparing hartoperation, VSARR

Outcome measures

Primary outcome

Reoperation

Secondary outcome

Survival outcome and Quality of life and Valve related complications.

Study description

Background summary

Provide insight in VSARR performed in Erasmus MC

Study objective

The main objective is to determine the early and late survival and reoperation outcome of VSARR in patients suffering from aortic root aneurysm with or without aortic regurgitation. Furthermore, we will evaluate the quality of using a SF-36 form. The second objective is evaluate the valve related complications after VSARR.

Study design

Single-centre hospital-based retrospective/prospective cohort study .

Study burden and risks

We expect that the burden associated with participation will be mainly emotional due to the SF-36 questionnaire. Patients have to visit our outpatient clinic which may have organizational burdens (taking a few ours off from work etc.) and to travel to the Erasmus MC..There is no further risk associated with participation because our study population consist of patients who are compos mentis and to collect our data, we use the hospital information systems. Patients may benefit from the knowledge of a potential change in the hemodynamics or change in valve function seen on the echocardiogram, which may

lead to an altered, improved treatment.

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

•All patients aged 18 years or older who received a valve sparing root reimplantation (Tirone David) at the Erasmus MC since 2000
•Signed informed consent by the patient and the investigator.

Exclusion criteria

•Patients who are unable or uncapable to give informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-12-2014
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	13-11-2014
Application type:	First submission
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	NL50604.078.14
Other	NTR nr volgt