Klinische controle na een klep-sparende hartoperatie

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24825

Source
NTR

Brief title
Tiron David

Health condition

outcome after valve sparing root replacement

Sponsors and support

Primary sponsor: Erasmus MC Rotterdam NL
Source(s) of monetary or material Support: not applicable

Intervention

Outcome measures

Primary outcome

Freedom of reoperation, survival and quality of life.

Secondary outcome

Valve related complications.

Study description

Background summary

Rationale: Provide insight in VSARR performed in Erasmus MC

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 population:
All patients who underwent an VSARR at an age above 18 years in the Erasmus MC since 2000 until now.

Intervention (if applicable): All patients will be asked to visit our outpatient clinic for an echocardiogram and to fill in a quality of life (SF-36) form.

Main study parameters/endpoints:
Reoperation and survival outcome. Secondary, valve related complications.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

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

Planned start 01-11-2014

Outpatient visits from 01-11-2014 until 01-06-2015.

Data collection from 01-11-2014 until 01-06-2015.

Writing manuscript and submission: 01-07-2015

Intervention

- TTE: transthoracic echocardiogram

- SF36: standardized "quality of life" form

Contacts

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Eligibility criteria

Inclusion criteria

• All patients aged 18 years or older who received a valve sparing root reimplantation (Tirone David) at the Erasmus MC since 2000, not reoperated on the aortic valve
Signed informed consent by the patient and the investigator.

Exclusion criteria

Patients who are unable to give informed consent.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2014
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-08-2014
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	NL4608

Register	ID
NTR-old	NTR4759
Other	: THCHOZ 2014-08

Study results

Summary results

• Does pregnancy influence the durability of human aortic valve substitutes?
Bardia Arabkhani, MSc, Helena J. Heuvelman, MD, MSc, Ad J.J.C. Bogers, MD, PhD, M. Mostafa Mokhles, MSc, Jolien W. Roos-Hesselink, MD, PhD, Johanna J.M. Takkenberg, MD, PhD. J Am Coll Cardiol. 2012;60(19):1991-1992. doi:10.1016/j.jacc.2012.06.055

• Outcome of Pregnancy in Women who received a Human or Mechanical Aortic Valve Substitute.
H.J. Heuvelman, MD, B. Arabkhani, P.G. Pieper, MD, PhD, J.J.M. Takkenberg, MD, PhD, J.M.J. Cornette, A.J.J.C. Bogers , MD, PhD, J.W Roos-Hesselink, MD, PhD. Am J Cardiol. 2012 Nov 20. doi:pii: S0002-9149(12)02293-X. 10.1016/j.amjcard.2012.09.035.

• Therapeutic decisions for patients with symptomatic severe aortic stenosis: room for improvement?
van Geldorp MW, van Gameren M, Kappetein AP, Arabkhani B, de Groot-de Laat LE, Takkenberg JJ, Bogers AJ. Eur J Cardiothorac Surg. 2009 Jun;35(6):953-7; discussion 957. Epub 2009 Mar 20.