Klinische controle na een klep-sparende hartoperatie

Gepubliceerd: 27-08-2014 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24825

Bron
NTR

Verkorte titel
Tiron David

Aandoening

outcome after valve sparing root replacement

Ondersteuning

Primaire sponsor: Erasmus MC Rotterdam NL
Overige ondersteuning: not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Freedom of reoperation, survival and quality of life.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

- TTE: transthoracic echocardiogram

- SF36: standardized "quality of life" form

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients who are unable to give informed consent.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2014
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-08-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4608
NTR-old	NTR4759
Ander register	: THCHOZ 2014-08

Resultaten

Samenvatting resultaten

• 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.