AVARIJN2 study

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We hypothesize that, asymptomatic patients with severe aortic stenosis, receiving an aortic valve replacement have a better quality of life compared to patients without aortic valve replacement.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21621

Bron
NTR

Verkorte titel
AVARIJN2 (Aortic VAlve RIJNMOND 2)

Aandoening

Aortic valve stenosis

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Department of Cardio-thoracic Surgery
Overige ondersteuning: Erasmus Medical Center, Department of Cardio-thoracic Surgery

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective is to determine the quality of life assessed with the SF-36V2¢â questionnaire in asymptomatic patients with severe aortic stenosis, the mortality (all-cause and specific cause) as well as the determination of the aortic valve function by an echocardiogram.

Toelichting onderzoek

Achtergrond van het onderzoek

The European as well as the American guidelines recommend aortic valve replacement (AVR) for patients with severe aortic stenosis (AS) having the concurrent symptoms related to AS (1, 2). Undergoing AVR for severe aortic stenosis results in better outcome compared to patients remaining asymptomatic and therefore not undergoing AVR (3). An overall improvement in functional quality of life, in patients undergoing AVR, has also been noted (4).

However, data focusing on asymptomatic patients is relative scarce. Recent studies did compare the operative and long-term cardiac mortality, as well as different parameters in asymptomatic (NYHA I) patients with severe aortic stenosis undergoing initial surgery versus a conservative treatment strategy (5, 6). Moreover, a randomized controlled trial, the AVATAR study, has begun recruiting patients, wherein they will be comparing an early surgery strategy with a watchful waiting strategy (7). The primary outcome measure, as described in published rationale and design paper of the AVATAR study, is a global composite of ‘hard’ endpoints including the all-cause mortality (7).

Whereas this study will provide new insight pertaining ‘hard’ endpoints as the mortality, quality of life assessment in a specific population has hardly been quantified, wherefore we want to conduct this study. To provide insight in the long-term follow-up focusing on the quality of life of patients with asymptomatic severe AS, also to depict the mortality and to evaluate the aortic valve function as obtained with an echocardiogram during the follow-up, to fully understand the effect severe aortic stenosis has in the asymptomatic population.

Hypothesis

We hypothesize that a significant proportion of patients with severe aortic stenosis is not referred for surgical treatment because of co-morbidities and/or old age, or is operated late in the course of the disease due to underestimation of disease severity and progression. We also hypothesize to see altered echocardiographic parameters in these asymptomatic severe AS patients.

Study objectives

Primary Objective(s): The primary objective is to determine the quality of life assessed with the SF-36V2 questionnaire in asymptomatic patients with severe aortic stenosis, the mortality (all-cause and specific cause) as well as the determination of the aortic valve function by an echocardiogram.

Secondary Objective(s): The secondary objective is to depict the emanated complications occurred during follow-up.

Study design

It is a hospital-based cohort study. All asymptomatic patients with severe aortic stenosis who participated in the AVARIJN-study will be selected. All patients who survived will be invited by telephone and letter to visit the outpatient clinic to undergo an echocardiogram and to fill the SF-36V2¢â Health Survey questionnaire. Further data will be obtained by the use of medical files and the hospital information system.

Methods

The asymptomatic patients included in the AVARIJN study will be provided with study information, and invited to the Erasmus Medical Center for participation in this study. Written informed consent will be obtained prior to participation. Echocardiographic inclusion criteria in the AVARIJN study was at least one of the following: (1) aortic valve area ≤1 cm2, (2) maximal trans aortic jet velocity ≥4 m/s, (3) peak aortic gradient ≥64 mmHg and (4) aortic valve / left ventricular outflow tract velocity time integral ratio ≥4.
Patient characteristics, functional status, quality of life and treatment undergone will be sought retrospectively. The patients will undergo an extra echocardiogram and have to fill in the SF-36V2 Health Survey questionnaire. We expect to include around 45 patients, as the study population of the AVARIJN study consists of 59 asymptomatic patients, with the expectation being to include between 85-95% of the eligible patients.

Doel van het onderzoek

We hypothesize that, asymptomatic patients with severe aortic stenosis, receiving an aortic valve replacement have a better quality of life compared to patients without aortic valve replacement.

Onderzoeksopzet

Accrual time: 01-07-2016 till 31-12-2017
Study end: 31-12-2018

Onderzoeksproduct en/of interventie

Retrospective follow-up of the asymptomatic patients in the AVARIJN study

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Adult patients, mentally competent and 18 years of age or older

- Inclusion in the AVARIJN study

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients who are not able 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:	01-07-2016
Aantal proefpersonen:	59
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL5731
NTR-old	NTR5918
Ander register	: MEC 16-417

Resultaten