Older AS-patients invasive therapy study: oASis, a prospective study.

Gepubliceerd: 24-01-2013 Laatst bijgewerkt: 18-08-2022

With the emergence of lesser invasive strategies to treat AS, it is expected that an increasing number of patients -who were previously not referred for invasive treatment for AS- will be referred to our center. Also, it is anticipated that with the...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26135

Bron
Nationaal Trial Register

Verkorte titel
OASIS pros

Aandoening

aortic valve disease
aortic stenosis

Ondersteuning

Primaire sponsor: Erasmus MC Dept. Cardio-thoracic Surgery
Overige ondersteuning: not funded

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Optimized multidisciplinary patient care.

Toelichting onderzoek

Achtergrond van het onderzoek

Background and rationale:

With the aging, it is expected that the health burden of aortic stenosis will increase considerably. Traditionally the treatment of symptomatic severe AS is AVR. However, a considerable proportion of patients is not referred for surgery, especially older patients with multiple co morbidities. Minimal invasive catheter techniques have been developed to implant a biological valve substitute in patients with severe AS.

There is a new and rapidly growing group of elderly patients with severe AS for whom these lesser invasive treatment methods are currently becoming available. This group of patients has a relatively short life expectancy and the weighing of costs and benefits of invasive treatment becomes increasingly important as the main goal of the treatment is to provide a better quality of life.
In addition, it is expected that in the future lesser invasive treatment methods will become available for younger patients with severe aortic valve disease of varying etiology.

Hypothesis:

With the emergence of lesser invasive strategies to treat AS, it is expected that an increasing number of patients will be referred to our center. Also, it is anticipated that more and more selected patients who previously underwent AVR will be treated using lesser invasive strategies.

Objectives:

It is proposed to initiate a prospective registry of all patients with severe aortic valve disease who are 18 years or older and are referred for invasive treatment of their aortic valve disease in order to ascertain a systematic uniform registration of patient characteristic, procedural aspects, and follow-up for the purpose of (1) optimized multidisciplinary patient care, (2) uniform scientific reporting, and (3) assessment of quality of care and referral trends over time.

Study design:

Prospective registry.

Study population:

Population: All patients with aortic valve disease age 18 years or older who are referred to Erasmus MC for the invasive treatment of aortic stenosis (AVR, TAVI, medical Tx).

Inclusion criteria:

Age 18 years and older, severe aortic valve disease with or without coronary artery disease, severe aortic stenosis with non-severe mitral regurgitation that may or may not require mitral valve surgery.

Exclusion criteria:

Severe mitral regurgitation.

Doel van het onderzoek

With the emergence of lesser invasive strategies to treat AS, it is expected that an increasing number of patients -who were previously not referred for invasive treatment for AS- will be referred to our center. Also, it is anticipated that with the expanding use of lesser invasive strategies to treat aortic valve disease, more and more selected patients who previously underwent AVR will be treated using lesser invasive strategies.

Onderzoeksopzet

1. Baseline;

2. Procedural;

3. 30 days;

4. 6 months;

5. 1 year.

Onderzoeksproduct en/of interventie

A systematic uniform registration of patient characteristic, procedural aspects, and follow-up for the purpose of:

1. Optimized multidisciplinary patient care;

2. Uniform scientific reporting;

3. Assessment of quality of care and referral trends over time.+ QoLSs*.

* QoLs : VAS, EQ5D, Katz ADL.

Given the anticipated expanding use of lesser invasive strategies to treat AS, the steadily growing elderly population with severe AS, and the increasing societal demand for highest quality at lowest cost care, there is an urgent need for systematic registration of this patient group and the effectiveness of the chosen treatment strategies.

Contactpersonen

Publiek

Erasmus MC
dept. Cardio thoracic surgery/Room Bd-573
's Gravendijkwal 230
J.J.M. Takkenberg
Rotterdam 3015 CE
The Netherlands
+31 (0)10 7035413

Wetenschappelijk

Erasmus MC
dept. Cardio thoracic surgery/Room Bd-573
's Gravendijkwal 230
J.J.M. Takkenberg
Rotterdam 3015 CE
The Netherlands
+31 (0)10 7035413

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age 18 years and older, severe aortic valve disease with or without coronary artery disease,

severe aortic stenosis with non-severe mitral regurgitation that may or may not require mitral valve surgery.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Severe mitral regurgitation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	07-12-2011
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-01-2013
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	NL3549
NTR-old	NTR3831
Ander register	METC Erasmus MC : 2011-489
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A