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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26135

Source
Nationaal Trial Register

Brief title
OASIS pros

Health condition

aortic valve disease
aortic stenosis

Sponsors and support

Primary sponsor: Erasmus MC Dept. Cardio-thoracic Surgery
Source(s) of monetary or material Support: not funded

Intervention

Outcome measures

Primary outcome

Optimized multidisciplinary patient care.

Secondary outcome

1. Uniform scientific reporting;

2. Assessment of quality of care and referral trends over time.

Study description

Background summary

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.

Study objective

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.

Study design

1. Baseline;

2. Procedural;

3. 30 days;

4. 6 months;

5. 1 year.

Intervention

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.

Contacts

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Eligibility criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-12-2011
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

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

Study results

Summary results
N/A