The Liar-Trial: patient reported health-related quality of life after LImited access and conventional Aortic valve Replacement.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac valve disorders
Study type	Interventional

Summary

ID

NL-OMON55420

Source
ToetsingOnline

Brief title
LIAR-Trial (LImited access Aortic valve Replacement-Trial)

Condition

- Cardiac valve disorders
- Cardiac therapeutic procedures

Synonym
aortic valve stenosis, heart valve restriction

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: access, limited, replacement, valve

Outcome measures

Primary outcome

The main objective of the LIAR-Trial is to provide evidence on improving health status, quality of life and postoperative pain sensation after limited access aortic valve surgery, measured by multiple validated health questionnaires.

Secondary outcome

Secondary objectives are aortic cross clamping time, cardio pulmonary bypass time, total operating time, technical success rate, complication rate, mortality rate, hospital length of stay, intensive care unit stay, reoperation rate, readmission rate and haemodynamic performance.

Study description

Background summary

Limited access aortic valve replacement leads to short-term advantage in both improvement in health status and reduced postoperative pain compared to conventional aortic valve replacement. This leads to early mobilization and faster recovery. The use of sutureless valves as a part of limited access cardiac surgery further enhances these beneficial effects, leading to a better and faster recovery postoperatively.

Study objective

The aim of this study is to compare health status, quality of life outcomes and subjective postoperative pain for patients with severe aortic stenosis treated

either with a limited access aortic valve replacement or with a conventional aortic valve replacement.

Study design

The LIAR-Trial is a single-centre randomised controlled trial to aim for improved health status and reduced pain postoperatively by using a ministernotomy for the placement of a sutureless aortic valve, compared to the placement of a sutureless aortic valve through the conventional full sternotomy.

Intervention

The intervention group will undergo a limited acces aortic valve replacement through ministernotomy, while the control group will undergo an aortic valve replacement through full sternotomy. Both groups will receive a sutureless valve.

Study burden and risks

The risks associated with participation in the trial concerning the limited access approach are comparable with the conventional approach. Furthermore, it has been demonstrated that the addition of a sutureless valve is feasible with good efficacy and safety. The burden for patients is also very low. They have to fill in two questionnaires at baseline, and postoperative pain sensation every day during their hospital length. During follow-up they have to fill in the two questionnaires and pain sensation four times during the first year. Five years after surgery we will ask the patients to fill out the quality of life questionnaires. Furthermore, we will evaluate the postoperative survival five years after surgery. Patients will receive an ultrasound of the heart according to regular practice and in accordance with the cardiologist.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients undergoing an aortic valve replacement for an aortic valve stenosis, defined as:
o An aortic valve area of <1.0cm2, and;
o Mean valve gradient of 40mmHg, and/or;
o A peak velocity of a least 4.0m/s.
- Able to understand the nature of the study and what will be required of them;
- All men and non-pregnant woman;
- BMI between 18-35.

Exclusion criteria

- Inability to give written informed consent;
- Patients requiring additional cardiac surgery during the same procedure;
- Patients requiring a reoperation (of the aortic valve);
- (relative) contraindications for a limited access approach;
- Undergoing an emergency operation;
- Recent myocardial infarction (<90 days);
- Recent stroke or transient ischemic attack (<6 months);
- Participation in a different heart-surgery related trial.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-06-2016
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	13-06-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-07-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL56311.100.16