A randomized prospective multicenter trial for stroke prevention by surgical occlusion of the left atrial appendage in patients undergoing aortic valve bioprosthetic surgery

Published: 07-03-2016
Last updated: 19-04-2024

The primary purpose of the LAA-CLOSURE trial is to assess the efficacy and safety of surgical closure of LAA in patients undergoing aortic valve replacement

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON50187

Source
ToetsingOnline

Brief title
LAA-CLOSURE

Condition

- Cardiac arrhythmias

Synonym
Atrial fibrillation, heart rhythm disorder

Research involving
Human

Sponsors and support

Primary sponsor: Cardiologie
Source(s) of monetary or material Support: Financiering via Topzorg

Intervention

Keyword: Aortic valve replacement, Atrial fibrillation, Left atrial appendage closure

Outcome measures

Primary outcome

- A composite of stroke, systemic embolism and cardiovascular mortality at 5

years

Secondary outcome

- Net adverse events (primary endpoint and major bleeding)

- Cardiovascular mortality

- Stroke

- Hospitalization for decompensated heart failure

- Major bleeding (BARC 3a, b, c or 5)

- Any bleeding (BARC 1, 2 3a, b, c or 5)

- Surgery related bleeding (BARC 4)

Study description

Background summary

Stroke is a relatively frequent long-term adverse event affecting up to 7-12% of patients at 5 years follow-up in patients undergoing aortic valve replacement surgery. In general population approximately every sixth stroke is due to atrial fibrillation (AF). Although the incidence and prevalence of AF are generally unknown in patients with operated aortic valve stenosis/regurgitation, high stroke risk may be an indicator of high AF burden. Previous studies have concluded that *90% of left atrial thrombi are located in

the left atrial appendage (LAA). Therefore LAA closure could be an alternative strategy for prevention of ischemic stroke. Current European Association of Cardiothoracic Surgery (EACTS) guidelines conclude that there is no proven benefit of surgical LAA exclusion in terms of stroke reduction or mortality benefit. The efficacy and safety of surgical closure of LAA have not been assessed in a large scale randomized clinical trial.

Study objective

The primary purpose of the LAA-CLOSURE trial is to assess the efficacy and safety of surgical closure of LAA in patients undergoing aortic valve replacement

Study design

Randomized, prospective, open-label international multicenter trial

Intervention

Investigational treatment: Surgical closure of left atrial appendage + standard aortic valve replacement with bioprosthesis according to clinical indication

Comparative treatment: Standard aortic valve replacement with bioprosthesis according to clinical indication

Study burden and risks

Risks: The additional risk of the LAA-closure is negligible.
Burden: Patients will be contacted by phone approximately 1, 3 and 5 years after surgery. At 12 months patients will be requested to fill out a questionnaire to assess quality of life.

Contacts

Public
Selecteer

Koekoekslaan 1
Nieuwegein 3435 cm
NL
Scientific
Selecteer

Koekoekslaan 1

Nieuwegein 3435 cm
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients undergoing aortic valve replacement (+/- coronary bypass AND/OR mitral valve surgery)
- Age *18 years
- No indication for long term anticoagulation at the time of enrollment.
- Patients with CHA2DS2-VASC score *2
- Patient or legally authorized representative has been informed of the nature of the study, agrees to its provisions and has been provided written informed consent, approved by the appropriate Medical Ethics committee or Institutional Review Board.

Exclusion criteria

- Age < 18 years
- Expected survival < 1 year
- Chronic atrial fibrillation
- Indication for long term anticoagulation therapy before the index procedure
- Mechanical valve implantation previously or at the index procedure

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-04-2016
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	07-03-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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

Approved WMO Date:	06-04-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	07-10-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	08-01-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-03-2022
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
ClinicalTrials.gov	NCT02321137
CCMO	NL55356.100.15