

# 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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Cardiac arrhythmias
<b>Study type</b>	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

## 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  $\geq 18$  years
- No indication for long term anticoagulation at the time of enrollment.
- Patients with CHA<sub>2</sub>DS<sub>2</sub>-VASC score  $\geq 2$
- 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