

# Antibiotics vs antibiotics and Surgical ThERapy for Infective endocarditis

Published: 23-06-2023

Last updated: 21-12-2024

To test whether valve surgery plus medical therapy is superior to medical therapy alone for treatment of endocarditis.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Cardiac valve disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON53957

### Source

ToetsingOnline

### Brief title

ASTERIx

## Condition

- Cardiac valve disorders
- Bacterial infectious disorders
- Cardiac therapeutic procedures

### Synonym

endocarditis, infection of the heart valve

### Research involving

Human

## Sponsors and support

**Primary sponsor:** University Hospital of Copenhagen, Rigshospitalet

**Source(s) of monetary or material Support:** Ministerie van OC&W, Novo Nordisk Foundation, The Danish Heart Foundation

## Intervention

**Keyword:** antibiotics, endocarditis, heart valve disease, valve surgery

## Outcome measures

### Primary outcome

A composite of one of the following criteria:

1. Death
2. New clinical stroke with persisting symptoms >24 hours from onset
3. New systemic embolization with clinical symptoms (e.g. clinical recognizable embolization by symptoms to brain, kidney, spleen, eyes, or extremities)
4. New endocarditis event (both relapse (relapse of bacteria with the same organism >7 days after study intervention, vegetation enlargement (>50%) or local spreading of the vegetation) and reinfection (new endocarditis episode after completed treatment for the initial endocarditis episode))
5. Unplanned hospitalization for new heart failure

### Secondary outcome

1. Individual components of the primary endpoint at study conclusion
2. Unplanned heart valve surgery due to infective endocarditis
3. End stage renal replacement therapy in a patient without this at randomization
4. Pacemaker or pacemaker extraction
5. Cause-specific mortality (cardiovascular and non-cardiovascular (infectious, malignancy, other, and unknown)
6. Days in hospital,
7. Clinical status at discharge (need for help with daily activities, use of

utilities for walking, home help, discharged to nursing facility, or disability pension)

## Study description

### Background summary

Infective endocarditis is a deadly disease (1/3 die within one year) and the incidence is increasing. An important initial assessment of patients with endocarditis includes whether surgical treatment is indicated; yet, appropriate data to guide this assessment do not exist. The current guidelines are based on low-level evidence and randomized data are desperately needed. The ASTERix study will be a novel randomized clinical trial testing a surgical approach in addition to medical therapy against a medical therapy alone approach for treatment of endocarditis.

### Study objective

To test whether valve surgery plus medical therapy is superior to medical therapy alone for treatment of endocarditis.

### Study design

Multicenter, international, randomized, prospective study.

Patients will be allocated by randomization to valve surgery plus medical therapy or medical therapy alone for treatment of endocarditis.

### Intervention

Valve surgery plus medical therapy versus medical therapy alone.

### Study burden and risks

Intervention:

1. Valve surgery plus antibiotics. Heart valve surgery is a high-risk surgical procedure. The actual risk associated with such surgery is highly dependent on the patient's medical history and the current severity of the disease. Current treatment guidelines encourage surgery; however, this is not really justified by the underlying evidence.
2. Antibiotics alone. If the hypothesis of this study is correct, disease progression may occur in some patients in the medical therapy only arm. As a

result of this deterioration, they will undergo heart valve surgery later in the treatment. Patients will be closely monitored during hospitalization for any progression of the disease.

Study measurements:

Only data from the patient's medical record are collected for this study. No additional measurements are taken. Routine clinical checks at 1 week, 4 weeks, 3 months, and 1 year after discharge are part of standard care.

## Contacts

### Public

University Hospital of Copenhagen, Rigshospitalet

Blegdamsvej 9  
Copenhagen 2100  
DK

### Scientific

University Hospital of Copenhagen, Rigshospitalet

Blegdamsvej 9  
Copenhagen 2100  
DK

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Definite left-sided infective endocarditis
- AND

- Valve vegetation  $\geq 10$  mm AND  $\leq 30$  mm with 1 or no previous embolic event during current infective endocarditis case

## Exclusion criteria

- Unwilling to sign informed consent
- At least one clear class I recommendation for surgery because of heart failure or uncontrolled local infection (abscess, false aneurysm, fistula)
- Unavailable for follow-up (e.g. tourist)

OR

At least one of the following criteria (unsuitable for surgery):

- Intracranial hemorrhage  $< 1$  month
- Life expectancy  $< 1$  year
- Age  $\geq 85$  years
- BMI below 15 or above 45
- Possible severe liver cirrhosis (Child-Pugh Class B or worse)
- Clinical frailty score of 6 or above
- EUROSCORE II  $> 50\%$
- Severe pulmonary disease (FEV1 or DLCO  $< 30\%$  of expected)
- Left ventricular ejection fraction  $< 20\%$
- Technically inoperable (e.g. extracorporeal circulation deemed impossible)

## 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:	Recruiting
Start date (anticipated):	08-10-2023
Enrollment:	60

Type: Actual

## Medical products/devices used

Registration: No

## Ethics review

Approved WMO

Date: 23-06-2023

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 07-11-2024

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

## 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

ClinicalTrials.gov

CCMO

### ID

NCT05061355

NL80848.058.22