# Antibiotics vs antibiotics and Surgical ThERapy for Infective endocarditis

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

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Cardiac valve disorders |
| **Study type** | 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

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## 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 =>10 mm AND <=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 >=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

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| 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 |

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| Type: | Actual |

### Medical products/devices used

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| Registration: | No |

## Ethics review

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| Approved WMO Date: | 23-06-2023 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

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| Approved WMO Date: | 07-11-2024 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>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 | ID |
|---|---|
| ClinicalTrials.gov | NCT05061355 |
| CCMO | NL80848.058.22 |