

# Acute endovascular treatment to improve outcome of ruptured aortoiliac aneurysms.

No registrations found.

|                              |                     |
|------------------------------|---------------------|
| <b>Ethical review</b>        | Positive opinion    |
| <b>Status</b>                | Recruitment stopped |
| <b>Health condition type</b> | -                   |
| <b>Study type</b>            | Interventional      |

## Summary

### ID

NL-OMON26237

### Source

NTR

### Brief title

the AJAX trial.

### Intervention

### Outcome measures

#### Primary outcome

Mortality and severe morbidity.

#### Secondary outcome

N/A

## Study description

### Background summary

Participants:

- 3 Hospitals: Academic Medical Center, VU Medical Center and Onze Lieve Vrouwe Gasthuis
- Randomized multicenter trial in the Amsterdam region.

## **Study objective**

Acute endovascular treatment improves outcome of ruptured aortoiliac aneurysms.

## **Study design**

N/A

## **Intervention**

1. CT angiography: all patients with suspected rupture of an abdominal aortic aneurysm will be examined by CT angiography to confirm the diagnosis of a ruptured aneurysm and to evaluate the anatomical suitability for endovascular treatment. The patient is entered in the study if the aneurysm is ruptured, the anatomical criteria for endovascular repair are fulfilled and the patient is fit for an open procedure.

Patients will then be randomized for either open or endovascular treatment. If possible informed consent is obtained, if the clinical condition of the patient does not allow for a proper informed consent, informed consent will be asked after the patient has been treated (in accordance with Dutch Law: WMO §2, artikel 6-1);

2. Open procedure: patient under general anesthesia, laparotomy, standard aortic repair with either an aortic tube graft or a bifurcated graft, standard closure.

3. Endovascular procedure: Local anesthesia of both groin regions, dissection of the common femoral arteries, placement of aorto-uni-iliac endovascular graft through one of the femoral arteries and placement of an iliac occluder in the contra lateral iliac artery, placement of a femoro-femoral cross-over bypass.

## **Contacts**

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## Eligibility criteria

### Inclusion criteria

1. Ruptured aneurysm (diagnosed by CT-angiography);
2. Anatomical criteria:
  - 2.1 Adequate infrarenal aortic neck;
  - 2.2 Adequate iliac anatomy.

### Exclusion criteria

1. Symptomatic aneurysm (no rupture);
2. Asymptomatic aneurysm;
3. Juxtarenal aneurysm;
4. Anatomical unsuitability;
5. Patient unfit for open procedure;
6. Extreme instability of the patient making CT-angiography impossible.

## Study design

## Design

|                     |                               |
|---------------------|-------------------------------|
| Study type:         | Interventional                |
| Intervention model: | Parallel                      |
| Allocation:         | Randomized controlled trial   |
| Masking:            | Single blinded (masking used) |
| Control:            | Active                        |

## Recruitment

|                           |                     |
|---------------------------|---------------------|
| NL                        |                     |
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 05-04-2004          |
| Enrollment:               | 0                   |
| Type:                     | Actual              |

## Ethics review

|                   |                  |
|-------------------|------------------|
| Positive opinion  |                  |
| Date:             | 17-06-2005       |
| Application type: | First submission |

## 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   |
|----------|------|
| NTR-new  | NL55 |

**Register**

NTR-old

Other

ISRCTN

**ID**

NTR85

: Dutch Heart Foundation 2002B197

ISRCTN66212637

## Study results

**Summary results**

N/A