Acute endovascular treatment to improve outcome of ruptured aortoiliac aneurysms.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26237

Source
Nationaal Trial Register

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	ID
NTR-old	NTR85
Other	: Dutch Heart Foundation 2002B197
ISRCTN	ISRCTN66212637

Study results

Summary results
N/A