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Acute endovascular treatment to improve outcome of ruptured aorto-iliac aneurysms

Submission date 12/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2005	**Overall study status** Completed	
Last Edited 19/03/2014	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR85; 2002B197

Study information

Scientific Title

Acronym
AJAX

Study objectives
Acute endovascular treatment improves outcome of ruptured aorto-iliac aneurysms.

Please note that as of 19/10/2007 the anticipated end date of this trial was extended from 01/10/2007 to 01/08/2008.

As of 12/09/2008 the anticipated end date was again extended to 01/10/2010. At this time, the record was also updated to include an enlarged target number of participants. The previous target number of participants was 80.

Patient inclusion completed with 116 patients on 17/02/2011

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the MEC of the Academic Medical Center in Amsterdam (certified MEC) on the 28th August 2003 (ref: MEC 03/161). A protocol amendment was approved on 26th November 2008.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ruptured aorto-iliac aneurysms

Interventions
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 randomised 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).

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

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 contralateral iliac artery, placement of a femoro-femoral cross-over bypass.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Mortality and severe morbidity, measured at 30 days, 3 months, 6 months.

Key secondary outcome(s))
1. Quality of life, measured at 30 days, 3 months, 6 months
2. Length of intensive care stay, measured at 30 days, 3 months, 6 months
3. Cost-effectiveness, measured at 30 days, 3 months, 6 months

Completion date
01/10/2010

Eligibility

Key inclusion criteria
1. Ruptured aneurysm (diagnosed by computed tomography [CT]-angiography)
2. Anatomical criteria:
2.1. Adequate infrarenal aortic neck
2.2. Adequate iliac anatomy

Added 12/01/2009:
3. Patients greater than 18 years male or female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key 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

Date of first enrolment
05/04/2004

Date of final enrolment
01/10/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Charity

Funder Name
Netherlands Heart Foundation (Nederlandse Hartstichting) (Netherlands) (ref: 2002B197)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2013		Yes	No
Results article	results	01/02/2014		Yes	No
Protocol article	Background, design, methods	01/05/2006		Yes	No
Other publications	Prospective cohort paper	01/06/2007		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes