

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

Submission date 12/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/03/2014	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.amc.nl/index.cfm?sid=324>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Patient information material can be found at: <http://www.amc.nl/index.cfm?pid=1132> (in Dutch only)

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 measure

Mortality and severe morbidity, measured at 30 days, 3 months, 6 months.

Secondary outcome measures

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

Overall study start date

05/04/2004

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

80 (this was amended on 12/01/2009 to 120 participants)

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)

Sponsor details

Department of Vascular Surgery
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor type

University/education

Website

<http://www.amc.uva.nl>

ROR

<https://ror.org/03t4gr691>

Funder(s)**Funder type**

Charity

Funder Name

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

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**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?
Protocol article	Background, design, methods	01/05/2006		Yes	No
Other publications	Prospective cohort paper	01/06/2007		Yes	No

Results article	results	01/08/2013	Yes	No
Results article	results	01/02/2014	Yes	No