ISRCTN48334791 https://doi.org/10.1186/ISRCTN48334791

Immediate management of patients with ruptured aneurysm: open versus endovascular repair

Submission date
02/12/2008

Recruitment status
No longer recruiting

Registration date
12/12/2008

Overall study status
Completed

Last Edited
06/06/2018

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Ruptured abdominal aortic aneurysm is a life-threatening condition where the main blood vessel of the body (the aorta) has swollen over many years (often silent with no obvious symptoms) and burst, causing extensive bleeding. Many patients with this condition do not survive to reach hospital alive. Until recently there was only one way to repair the ruptured aneurysm. This involved major surgery with a large cut in the tummy and replacement of the diseased aorta with a plastic (Polyester) tube (open surgery). However, after this major emergency surgery only about half of the patients leave hospital alive. A new 'keyhole' technique of aneurysm repair, called endovascular repair, has made it possible to re-line the ruptured aorta using a stent introduced through two small cuts in the groin (endovascular repair). However, only about 60% of patients are anatomically suitable for endovascular repair. At present we do not know which of the treatments is best for people with this condition. Therefore, this study aims to find out whether a strategy of preferential emergency endovascular repair reduces both the mortality (death rate) and cost of ruptured abdominal aortic aneurysm.

Who can participate?
Patients over the age of 50 who are suspected of having ruptured abdominal aortic aneurysm after review in Accident and Emergency (or other hospital unit)

What does the study involve?
Participants are randomly allocated, in the emergency room, to either a strategy of endovascular repair if possible (endovascular strategy) or to the current standard care (immediate transfer to the operating theatre for emergency open surgery). Patients allocated to the endovascular strategy undergo a special X-ray scan (CT scan) to assess anatomical suitability and plan for endovascular repair. This causes a short delay before definitive repair can begin: the study finds out whether this delay is dangerous. Those patients not suitable for endovascular repair after CT scan are taken for standard open surgery and the others have endovascular repair. Participants' survival within 30 days of surgery is measured, which it is hoped will improve by 14% with the

endovascular strategy. Survival at hospital discharge and after 12 months, the costs of each treatment, quality of life and cost-effectiveness are also measured. It is hoped that these will improve with endovascular repair.

What are the possible benefits and risks of participating?
Ruptured abdominal aortic aneurysm is an immediately life-threatening condition. Without an operation patients do not survive. Consequently, operations to save patients' lives are associated with major complications. However, it is very unlikely that research participants will suffer any additional pain, discomfort, distress or inconvenience beyond patients not participating in the research. Patients who have received an endovascular repair will continue to be monitored for device complications under standard NHS care.

Where is the study run from?
The study co-ordinating centre is based at the Vascular Surgery Research Group, Imperial College London. The study will be conducted in about 20 specialist hospital centres in the UK (and one large centre in Canada), which have already attained sufficient experience in using endovascular repair for ruptured aneurysms and can offer a routine service of emergency endovascular repair.

When is the study starting and how long is it expected to run for?
April 2009 to March 2017

Who is funding the study?
National Institute for Health Research Health Technology Assessment Programme (UK)

Who is the main contact?
1. Prof. Janet Powell
j.powell@imperial.ac.uk
2. Dr Pinar Ulug
improvetrial@imperial.ac.uk

Study website
http://www.improvetrial.org/

Contact information

Type(s)
Scientific

Contact name
Prof Janet Powell

ORCID ID
http://orcid.org/0000-0002-3905-1468

Contact details
Vascular Surgery Research Group
Imperial College London
Charing Cross Campus
St Dunstans Road
London

United Kingdom
W6 8RP
+44 (0)20 8846 7312
j.powell@imperial.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00746122

Secondary identifying numbers
HTA 07/37/64

Study information

Scientific Title
Can emergency endovascular aneurysm repair (eEVAR) reduce mortality from ruptured abdominal aortic aneurysm (AAA)?

Acronym
IMPROVE

Study objectives
Ruptured abdominal aortic aneurysm is the bursting of the main blood vessel of the body (the aorta) in the belly, which causes death in over 85% of cases. An attempt at open surgical repair is made in less than half of those who arrive at hospital alive and of those receiving surgical repair only half will be alive at 30 days.

It is possible that application of new minimally invasive technology (endovascular aneurysm repair [EVAR]) would greatly improve the number of patients alive at 30 days. However not all patients are anatomically suitable for endovascular repair.

The principal research question is, to be addressed in a randomised clinical trial is:
Can a strategy of preferential endovascular repair of ruptured abdominal aortic aneurysm, versus the current practice of open surgical repair, significantly reduce the 30 day mortality of this condition?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. South Central - Berkshire Research Ethics Committee, 22/12/2008, ref: 08/H0505/173
2. Scotland A Research Ethics Committee, 19/12/2008, ref: 08/MRE00/90
3. University of Western Ontario Health Sciences Research Ethics Board (HSREB), 14/06/2011, ref: 17698

Study design
Randomised controlled multi-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: http://www1.imperial.ac.uk/biosurgerysurgicaltechnology/clinical_trials_outcomes/vasculardisease/clinicaltrials/improvetrial/healthcare_professionals/resources/

Health condition(s) or problem(s) studied
Abdominal aortic aneurysm

Interventions
The patients will be randomised to a strategy of EVAR if anatomically suitable (EVAR first) or to the standard emergency open surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
30-day mortality

Secondary outcome measures
As of 18/08/2016:
1. Mortality at 24-hour, in-hospital, and 1-year and 3-years after the rupture
2. Complications and re-interventions related to ruptured AAA repair in 1 year and 3 years
3. Major morbidity (stroke, myocardial infarction, renal or respiratory failure) in 1 year
4. Accuracy of clinical diagnosis of ruptured abdominal aortic aneurysm
5. Cost and Cost-effectiveness

Initial
1. Mortality at 24-hour, in-hospital, and 1-year after the rupture
2. Complications and re-interventions related to ruptured AAA repair in 1 year
3. Major morbidity (stroke, myocardial infarction, renal or respiratory failure) in 1 year
4. Accuracy of clinical diagnosis of ruptured abdominal aortic aneurysm
5. Cost-effectiveness

Overall study start date
01/04/2009

Completion date
31/03/2017

Eligibility

Key inclusion criteria
1. Both males and females, over the age of 50 years
2. Clinical suspicion of ruptured abdominal aortic aneurysm after review in Accident and Emergency (or other hospital unit)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
600

Key exclusion criteria
1. Patients with known connective tissue disorders (e.g., Marfan syndrome) where endovascular repair may not be beneficial
2. Patients with known previous repair of an abdominal aortic aneurysm, because procedures either open or endovascular are likely to be very complex and there are no guidelines for anatomical restriction to repair
3. Deeply unconscious and moribund patients since the chances of recovery are minimal

Date of first enrolment
16/09/2009

Date of final enrolment
21/07/2013

Locations

Countries of recruitment
Canada

England

United Kingdom

Study participating centre
Imperial College London
London

United Kingdom
W6 8RP

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
Research Governance Office
Faculty of Medicine
G02 Sir Alexander Fleming Building
South Kensington Campus
London
England
United Kingdom
SW7 2AZ

Sponsor type
University/education

Website
http://www3.imperial.ac.uk/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Publications and reporting is expected in early 2014 (short-term results) and 2017 (long-term results).

Intention to publish date
01/09/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from mjs212@medschl.cam.ac.uk after approval by the Trial Management Committee.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/08/2009		Yes	No
Protocol article	protocol	01/11/2009		Yes	No
Results article	results	13/01/2014		Yes	No
Results article	results	01/02/2014		Yes	No
Results article	results	01/04/2014		Yes	No
Results article	results	01/06/2015		Yes	No
Results article	results	14/08/2015		Yes	No
Results article	results	01/09/2015		Yes	No
Results article	results	01/09/2015		Yes	No
Results article	results	14/11/2017		Yes	No
Results article	results	01/05/2018		Yes	No
Results article	results	01/05/2018		Yes	No