

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

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|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>02/12/2008   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>12/12/2008 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results            |
| <b>Last Edited</b><br>06/06/2018       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> 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](mailto:j.powell@imperial.ac.uk)

2. Dr Pinar Ulug

[improvetrial@imperial.ac.uk](mailto:improvetrial@imperial.ac.uk)

**Study website**

<http://www.improvetrial.org/>

## Contact information

**Type(s)**

Scientific

**Contact name**

Prof Janet Powell

**ORCID ID**

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**Contact details**

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## **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/vascular-disease/clinicaltrials/improvetrial/healthcare\\_professionals/resources/](http://www1.imperial.ac.uk/biosurgerysurgicaltechnology/clinical_trials_outcomes/vascular-disease/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? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a> | protocol | 01/08/2009   |            | Yes            | No              |
| <a href="#">Protocol article</a> | protocol | 01/11/2009   |            | Yes            | No              |
| <a href="#">Results article</a>  | results  | 13/01/2014   |            | Yes            | No              |
| <a href="#">Results article</a>  | results  | 01/02/2014   |            | Yes            | No              |
| <a href="#">Results article</a>  | results  | 01/04/2014   |            | Yes            | No              |
| <a href="#">Results article</a>  | results  | 01/06/2015   |            | Yes            | No              |
| <a href="#">Results article</a>  | results  | 14/08/2015   |            | Yes            | No              |
| <a href="#">Results article</a>  | results  | 01/09/2015   |            | Yes            | No              |
| <a href="#">Results article</a>  | results  | 01/09/2015   |            | Yes            | No              |
| <a href="#">Results article</a>  | results  | 14/11/2017   |            | Yes            | No              |
| <a href="#">Results article</a>  | results  | 01/05/2018   |            | Yes            | No              |
| <a href="#">Results article</a>  | results  | 01/05/2018   |            | Yes            | No              |