# Information sheets and consent forms for "Can emergency endovascular aneurysm repair reduce the mortality from ruptured abdominal aortic aneurysm?"

## Table of contents

# Information sheets and consent forms: England & Wales

**Pre-operative patient information sheet and consent/emergency enrolment forms**

**Must be printed on Trust headed paper, with name and contact details of the lead clinician**

IMPROVE trial

**I**mmediate **M**anagement of the **P**atient with **R**upture:
**O**pen **V**ersus **E**ndovascular repair

Ethics Ref No: 08/H0505/173

# Information sheet to be read to the patient in England, Wales and Northern Ireland:

You have a life-threatening condition where a major blood vessel has burst in your tummy. You need major surgery (an operation) on your tummy to repair the blood vessel and try to save your life.

*Pause whilst the doctor waits for the patient to respond*

There are two methods of doing this operation. The standard method involves cutting open your tummy and replacing the burst blood vessel. The second is a new 'keyhole' technique that involves re-lining the bleeding blood vessel through the artery in your groin: this requires a special X-ray scan first and may lead to a slight delay with this treatment.

We do not know which treatment is best. So, we would like your permission to enter you into a trial where we choose at random which operation you have.

The urgency of the situation means that we will discuss in detail what has happened after your operation.

You are under no obligation to take part in this study. If you decline, your care will not be compromised and you probably will have the standard open operation rather than the new treatment.

**IMPROVE Trial Contacts:**

**Trial Chief Investigator:** Professor Janet T Powell
E-mail: j.powell@imperial.ac.uk
Tel: 020 3311 7312
Fax: 020 3311 7330

**Trial Manager:** Dr Pinar Ulug
E-mail: p.ulug@imperial.ac.uk
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Vascular Surgery Research Group, Imperial College at Charing Cross Hospital
St. Dunstan's Road, London W6 8RP

**IMPROVE England, Wales & Northern Ireland**
**Ethics Ref No: 08/H0505/173**

**Patient ID** | | | | |

IMPROVE trial

Immediate **M**anagement of the **P**atient with **R**upture:
**O**pen **V**ersus **E**ndovascular repair

# CONSENT FORM
# for England, Wales and Northern Ireland

**I, ……., have**
*<insert name of person taking consent>*

**read the statement overleaf to ……..**
*<insert name and underline status of person* ***(patient/relative/carer)*** *giving consent>*

**Verbal / written consent has been given for ……**
*< Insert name of patient>*

**to be entered into the IMPROVE trial.**

**Signed** **Date**
*(patient/relative/carer)*

**Signature of person taking consent** **Date**

**Title/Name:**


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St. Dunstan's Road, London W6 8RP


**Local Hospital:** _____
**Local Contact:** _____

IMPROVE trial

Immediate **M**anagement of the **P**atient with **R**upture:
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# EMERGENCY ENROLMENT FORM

## for England, Wales and Northern Ireland:

**Enrolment when patient/relative/carer consents unavailable**

**I, …… , agree the diagnosis of**
*<insert name of person enrolling patient>*

**ruptured abdominal aortic aneurysm in ……**
*<insert name of patient>*

**The patient cannot give informed consent and no relatives or carers are available for immediate consultation.**

**Signature of enroller** **Date**

**Title/Name:**

**Witnessed: I agree that verbal / written consent cannot be obtained for this patient.**

**Name of witness: ……..**

**Signature of witness**

**Title/Name:**

**IMPROVE Trial Contacts:**

**Trial Chief Investigator:** Professor Janet T Powell
E-mail: j.powell@imperial.ac.uk
Tel: 020 3311 7312 Fax: 020 3311 7330

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Vascular Surgery Research Group, Imperial College at Charing Cross Hospital
St. Dunstan's Road, London W6 8RP

**Local Hospital:** _____

**Local Contact:** _____

**Post-operative patient information sheets after open surgery and endovascular repair**

**Must be printed on Trust headed paper, with name and contact details of the local Principal Investigator**

IMPROVE trial

**I**mmediate **M**anagement of the **P**atient with **R**upture:
**O**pen **V**ersus **E**ndovascular repair

Ethics Ref No: 08/H0505/173

## Post-operative Patient Information after Open Surgery

### Summary

You have suffered a ruptured abdominal aortic aneurysm. This is a condition where the main blood vessel in your tummy has swollen over many years and burst causing extensive bleeding. Many patients with your condition do not survive to reach hospital alive. Of those that reach hospital alive only 50% will survive the operation to repair the aorta and stop the bleeding.

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). Recent technical advances have made it possible to re-line the ruptured aorta using a stent introduced through two small cuts in the groin (endovascular repair). However, at present we do not know which of the treatments is best for people with your condition.

You have been enrolled in a trial involving a number of specialist UK hospitals. The trial compares the two techniques for repair of ruptured abdominal aortic aneurysm in many patients. When you were admitted to hospital you consented to receive either open surgery or endovascular repair. The treatment was randomly allocated so we did not know which treatment you were to receive until you entered the trial. You received an open repair, and we shall advise your GP of this when you leave hospital.

**IMPROVE Trial Contacts:**

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Fax: 020 8846 7330

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Tel: 020 8383 3651
Fax: 020 8846 7318

Vascular Surgery Research Group, Imperial College at Charing Cross Hospital
St. Dunstan's Road, London W6 8RP

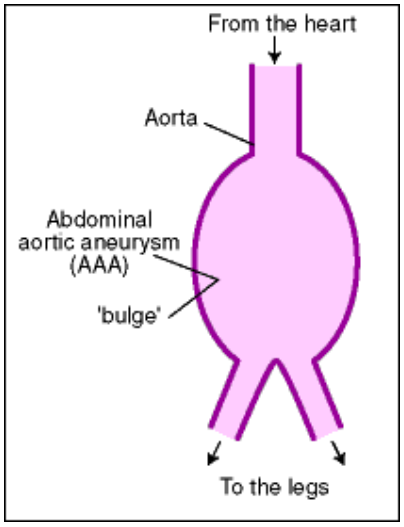
**Local Contact:** _____

You are under no obligation to continue in the study and you may withdraw any time without giving a reason. If you withdraw from the study, your care will not be compromised and you will be offered standard follow-up. In your case this usually comprises one or two clinic visits post-operatively.

If you wish to remain in the trial you will be asked to attend two clinic appointments in the first post-operative year and will be required to reply to two questionnaires (see schedule). We also shall ask for your permission to review your hospital notes for up to 5 years after your operation.

**What is an AAA?**

An aneurysm is a localised, balloon-like stretching of a weakened artery (blood vessel) wall. Although this can happen to any artery in the body, the most commonly affected vessel is the aorta which is the main central artery in the body. It carries blood from the heart down through the chest and abdomen (stomach) and branches out to all of the body's major organs. A normal aorta is about 1.5-2.5cm (¾ -1 inch) in diameter.




This diagram shows what your aorta looks like with an aneurysm

Aortic aneurysms are often silent with no obvious symptoms. However, about 1 in 4 patients will experience some symptoms such as tenderness in the chest or stomach area, back pain and/or reduced blood flow to their legs. When an abdominal aortic aneurysm increases in size, and particularly when the diameter is 5.5cm (2 ¼ inches) or greater, there is an increasing risk that the artery wall will leak or even burst. This is known as a "rupture" and leads to dangerous bleeding inside the body.

**Ruptured abdominal aortic aneurysm**

A ruptured aneurysm can be associated with severe pain in the stomach or back area, a rapid heart beat, a pulsing sensation in the stomach and skin feeling “cold and sweaty”. Only 2 in 10 people survive an aortic aneurysm rupture and just half of all patients manage to get to a hospital at all. About 12 000 people die from ruptured aneurysms in U.K. every year.

**What causes an abdominal aortic aneurysm?**

Aortic aneurysm can occur when the wall of the aorta has been damaged and weakened by one or more of the possible risk factors such as:

- Smoking
- High blood pressure
- Atherosclerosis - build up of fatty deposits leading to deterioration of the artery wall and loss of elasticity
- Inherited aortic wall weakness / family history
- Age

Infection and injury are also thought to be possible causes for the artery to expand and form an aneurysm.

**Who gets an abdominal aortic aneurysm?**

Aneurysms occur in approximately 1 in 20 men over the age of 65. They are four to five times more common in men than women. There is also an increased risk of a younger man developing an aneurysm if his father, mother or brother has been diagnosed with the condition.

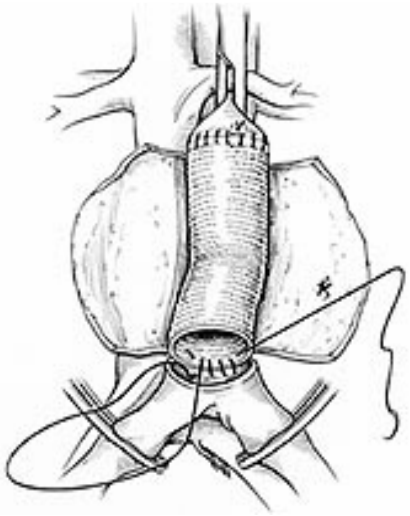
**How is abdominal aortic aneurysm diagnosed?**

As an aneurysm is often symptom free, it is frequently diagnosed by chance when a patient is being examined for another problem or undergoing an x-ray or ultrasound scan for a different reason. Alternatively, a patient may visit their doctor due to stomach or back pain which needs to be investigated. An ultrasound scan is a very good way to tell if there is an aneurysm present and how large it is. This is a quick and painless procedure, which is commonly used for scanning pregnant women, where a hand-held scanning device is passed over the skin on the stomach using special gel. The resulting sound waves are used to build pictures of the internal organs which can be used to diagnose and follow the changes in size of an aneurysm. If an aneurysm is suspected, a doctor or hospital consultant will refer the patient to hospital for an ultrasound scan. An alternative method for the detection of aneurysms is called a CT scan (computerised tomography). This

involves being placed inside a sophisticated X-ray scanner. A CT scan is the best way to confirm the aneurysm has ruptured.

**What is open surgical repair of an abdominal aortic aneurysm?**

This method of aortic aneurysm repair was developed in the mid-1950s. It is a major operation carried out by Vascular Surgeons in an operating theatre and the patient is given a general anaesthetic. A large cut, starting from just below the chest, is usually made lengthways to the abdomen to expose the aorta and clamps are temporarily placed above and below the aneurysm to shut off the blood flow through the vessel and stop the bleeding. Blood flow to the legs is interrupted while the aorta is clamped. This is not usually a problem as heparin is given to prevent the blood from clotting. The aneurysm is cut open and any blood clot or debris is removed from within it. The artificial graft is then sewn onto the blood vessel at the top and bottom of the aneurysm sac where there is no disease, so that it lies within what was the inside of the aneurysm. When the clamps have been removed and blood flow is re-established without any leaks, the wall of the aneurysm is closed over the graft to protect it. Patients will require a blood transfusion during or after the operation to replace several litres which is typically lost during the procedure although this amount may be much greater in difficult or prolonged operations. The surgery usually takes 2 – 3 hours to complete.



This diagram shows an artificial graft being sewn into the artery inside the aneurysm.

**Hospital stay, recovery time and follow-up:**

Most patients will spend several days or longer after an open repair in an Intensive Care Unit (ICU). They will remain in hospital for a total of 7-10 days or more. Full recovery from a major operation of this type can typically take up to 3-6 months. Long term complications after a successful repair are comparatively rare. The grafts are

known to last for 20-30 years and so patients do not need further follow-up appointments beyond twelve months after a successful repair for aneurysm rupture.

**What are the risks and complications associated with open surgical repair?**

Ruptured aortic aneurysm is an immediately life threatening procedure. Without an operation patients do not survive. Consequently operations to save patients lives are associated with major complications, which include heart attack, stroke, kidney failure, chest and wound problems.

**Follow-up schedule for continued participation in the trial:**

| | **Open surgery** |
|---|---|
| **Clinic visits** | 3 months after operation<br>12 months after operation |
| **Questionnaires** | 3 months after operation<br>12 months after operation |
| **Hospital note review** | Until 5y after operation |

**Will my taking part in this study be kept confidential?**

If you agree to continue in this trial, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the team organising the research. They may also be looked at by representatives of regulatory authorities and by authorised people to check that the study is being carried out correctly. The NHS Information Centre and NHS Central Register may use this information to help contact you and provide information about your health status. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

**Who has reviewed this study (the IMPROVE trial)?**

The Health Technology Assessment programme of the National Institute for Health Research is supporting this study. The study has received a favourable ethical opinion for conduct by the Berkshire Research Ethics Committee and the Scotland A Research Ethics Committee.

**What if something goes wrong?**

Imperial College London (the trial Sponsor) holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Chief Investigator *(Professor Janet T. Powell) and local Principal Investigator, whose contact details have been provided on page 1.* The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College Joint Research Office.

**Further information**

If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the procedures involved.

If you would like to read more about this trial you can contact:

Name:

Telephone/ Email:

Study website: www.improvetrial.org

ClinicalTrials.gov Identifier: NTC00746122 www.clinicaltrials.gov

**Must be printed on Trust headed paper, with name and contact details of the local Principal Investigator**

IMPROVE trial

**I**mmediate **M**anagement of the **P**atient with **R**upture:
**O**pen **V**ersus **E**ndovascular repair

Ethics Ref No: 08/H0505/173

## Post-operative Patient Information after Endovascular Repair

### Summary

You have suffered a ruptured abdominal aortic aneurysm. This is a condition where the main blood vessel in your tummy has swollen over many years and burst causing extensive bleeding. Many patients with your condition do not survive to reach hospital alive. Of those that reach hospital alive only 50% will survive the operation to repair the aorta and stop the bleeding.

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). Recent technical advances have made it possible to re-line the ruptured aorta using a stent introduced through two small cuts in the groin (endovascular repair). However, at present we do not know which of the treatments is best for people with your condition.

You have been enrolled in a trial involving a number of specialist UK hospitals. The trial compares the two techniques for repair of ruptured abdominal aortic aneurysm in many patients. When you were admitted to hospital you consented to receive either open surgery or endovascular repair. The treatment was randomly allocated so we did not know which treatment you were to receive until you entered the trial. You received an endovascular repair, and we shall advise your GP of this when you leave hospital.

**IMPROVE Trial Contacts:**

**Trial Chief Investigator:** Professor Janet T Powell
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Vascular Surgery Research Group, Imperial College at Charing Cross Hospital
St. Dunstan's Road, London W6 8RP

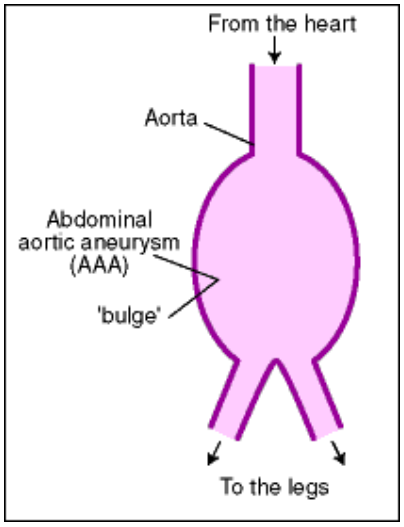
**Local Contact:** _____

You are under no obligation to continue in the study and you may withdraw any time without giving a reason. If you withdraw from the study, your care will not be compromised and you will be offered standard follow-up. Most surgeons suggest at least yearly scans and clinic visits following endovascular repair to ensure it continues to work effectively.

If you wish to remain in the trial you will be asked to attend two clinic appointments and 2 CT scans in the first post-operative year and will be required to reply to two questionnaires (see schedule).

**What is an AAA?**

An aneurysm is a localised, balloon-like stretching of a weakened artery (blood vessel) wall. Although this can happen to any artery in the body, the most commonly affected vessel is the aorta which is the main central artery in the body. It carries blood from the heart down through the chest and abdomen (stomach) and branches out to all of the body's major organs. A normal aorta is about 1.5-2.5cm (¾ -1 inch) in diameter.




This diagram shows what your aorta looks like with an aneurysm

Aortic aneurysms are often silent with no obvious symptoms. However, about 1 in 4 patients will experience some symptoms such as tenderness in the chest or stomach area, back pain and/or reduced blood flow to their legs. When an abdominal aortic aneurysm increases in size, and particularly when the diameter is 5.5cm (2 ¼ inches) or greater, there is an increasing risk that the artery wall will leak or even burst. This is known as a "rupture" and leads to dangerous bleeding inside the body.

**Ruptured abdominal aortic aneurysm**

A ruptured aneurysm can be associated with severe pain in the stomach or back area, a rapid heart beat, a pulsing sensation in the stomach and skin feeling “cold and sweaty”. Only 2 in 10 people survive an aortic aneurysm rupture and just half of all patients manage to get to a hospital at all. About 12 000 people die from ruptured aneurysms in U.K. every year.

**What causes an abdominal aortic aneurysm?**

Aortic aneurysm can occur when the wall of the aorta has been damaged and weakened by one or more of the possible risk factors such as:

- Smoking
- High blood pressure
- Atherosclerosis - build up of fatty deposits leading to deterioration of the artery wall and loss of elasticity
- Inherited aortic wall weakness / family history
- Age

Infection and injury are also thought to be possible causes for the artery to expand and form an aneurysm.

**Who gets an abdominal aortic aneurysm?**

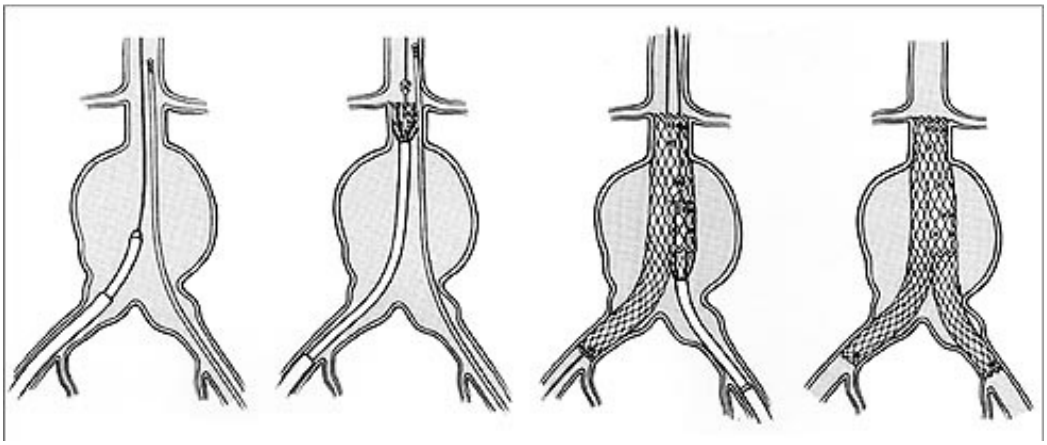
Aneurysms occur in approximately 1 in 20 men over the age of 65. They are four to five times more common in men than women. There is also an increased risk of a younger man developing an aneurysm if his father, mother or brother has been diagnosed with the condition.

**What is Endovascular stent-graft repair (EVAR) of an abdominal aortic aneurysm?**

EVAR was developed in the early 1990s by surgeons in the Ukraine and Argentina as a less invasive alternative to open aneurysm repair. The procedure is carried out by a specialised team sometimes including both Vascular Surgeons and Interventional Radiologists. As the patient can be given a local anaesthetic instead of a general anaesthetic, the repair can be carried out either in an operating theatre or in an angiography suite in the Radiology Department.

A small cut is made in each groin to allow access to the femoral arteries and catheters are passed through these arteries into the aneurysm. Using X-ray for guidance, the synthetic endovascular stent-graft is passed through the catheters up to the aneurysm and positioned at the top and bottom of the diseased part of the

aorta. The main body of the graft is located in the aorta and the legs extend down from the main body into the iliac arteries. The stent-graft is then expanded inside the aneurysm and fastened in place by metal stents to form a new stable channel for blood flow and seals off (excludes) the aneurysm. The graft strengthens the weakened aorta wall and prevents the aneurysm from rupturing.



This diagram shows the catheter being passed up through the aneurysm and then the stent –graft being passed up through the catheters. It is positioned at the top and bottom parts of the aneurysm and expanded to fasten in place.

There may be a need for additional endovascular or surgical procedures before, during or after the main procedure in order to complete the EVAR deployment successfully. These may include stents in the iliac arteries, “blocking off” of selected arteries or bypass grafting. Endovascular repair usually takes 2 to 3 hours to complete. During this period the correct positioning of the graft requires further X-ray studies and hence exposure to further radiation.

Most patients will spend time in a High Dependency or Intensive Care unit and will remain in hospital for a total of 4-6 days. It is possible to return to normal activity within 4 to 6 weeks. Because the long term results of endovascular repair have not yet been established, it is required that patients attend routine follow-up visits at the hospital for the rest of their life. They also need to have a CT scan every year to monitor the status of both the old aneurysm and the endovascular stent-graft.

**What are the risks and complications with treatment?**

Ruptured aortic aneurysm is an immediately life threatening procedure. Without an operation patients do not survive. Consequently operations to save patients lives are

associated with major complications. These include heart attack, stroke, kidney failure or chest problems, and can be fatal. In a minority of cases, there may be a small amount of new bleeding or the new graft in your aorta may move slightly and threaten the integrity of the repair.

**Computed Tomography (CT) scan**

This permits your doctors to see how well the new graft in your aorta is working. In order to obtain a CT scan, the patient has to lie flat on his / her back in the CT scanner and extend both arms above the head. The scanner reviews the patient's body and breaks it down into a series of "slices"; the thickness of which can be chosen at the beginning of the scan. These "slices" are then used to build a picture of the inside of the body and the thinner the slices, the greater the amount of detail and information that can be obtained. This will allow your doctors to check that there is no renewed bleeding and that the graft is staying in its original position. The CT scan will expose you to some radiation, but this radiation is unlikely to increase your risk of developing cancer.

**Follow-up schedule:**

| | **Endovascular repair** |
|---|---|
| **Clinic visit** | 3 months after operation<br>12 months after operation |
| **CT scan** | 3 months after operation<br>12 months operation |
| **Questionnaire** | 3 months after operation<br>12 months after operation |
| **Hospital notes review** | Up to 5 years after operation |
| **Health status check** | Beyond 12 months |

**Will my taking part in this study be kept confidential?**

If you agree to continue in this trial, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the team organising the research. They may also be looked at by representatives of regulatory authorities and by authorised people to check that the study is being carried out correctly. The NHS Information Centre and

NHS Central Register may use this information to help contact you and provide information about your health status. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

**Who has reviewed this study (the IMPROVE trial)?**

The Health Technology Assessment programme of the National Institute for Health Research is supporting this study. The study has received a favourable ethical opinion for conduct by the Berkshire Research Ethics Committee and the Scotland A Research Ethics Committee.

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If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Chief Investigator *(Professor Janet T. Powell) and local Principal Investigator, whose contact details have been provided on page 1.* The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College Joint Research Office .

**Further information**

If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the procedures involved. If you would like to read more about this trial you can contact:

Name:

Telephone/ Email:

Study website: www.improvetrial.org

ClinicalTrials.gov Identifier: NTC00746122 www.clinicaltrials.gov

## Post-operative consent form

**Must be printed on Trust headed paper, with name and contact details of the local Principal Investigator**

IMPROVE trial

**I**mmediate **M**anagement of the **P**atient with **R**upture:
**O**pen **V**ersus **E**ndovascular repair
Ethics Ref No: 08/H0505/173

**Patient ID:** ☐☐☐☐

# POST-OPERATIVE CONSENT FORM
## for England, Wales and Northern Ireland

**The post-operative information sheet dated 5th March 2010** (version 4.1) **has been read by:**

**……**
*<insert name of patient>*

**They have agreed to their continued participation in the IMPROVE Trial.**

**……**
*<patient signature / initials>*

**They have also agreed to their personal data being kept for up to 5 years. Further information about their health status may be obtained from NHS Information Centre and NHS Central Register.**

**……**
*<patient signature / initials>*

**Signed** *(patient)* **Date**

**Signature of person taking consent** **Date**

**Title/Name:**

**When completed, original to be kept in medical notes, one copy for patient, one copy for investigator site file**

**IMPROVE Trial Contacts:**

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E-mail: j.powell@imperial.ac.uk
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Tel: 020 8383 3651 Fax: 020 8846 7318

Vascular Surgery Research Group, Imperial College at Charing Cross Hospital
St. Dunstan's Road, London W6 8RP

**Local Contact:** _____

**Post-operative consultee information sheets after open surgery and endovascular repair**

**Must be printed on Trust headed paper, with name and contact details of the local Principal Investigator**

IMPROVE trial

**I**mmediate **M**anagement of the **P**atient with **R**upture:
**O**pen **V**ersus **E**ndovascular repair

Ethics Ref No: 08/H0505/173

# Information for Consultees for patients having had Open Surgery

**Your role as a Consultee**

You are acting on behalf of a patient enrolled in a trial of emergency repair of abdominal aortic aneurysm, where enrolment was under the authority of the Mental Capacity Act, as recommended by Berkshire Research Ethics Committee. This happened because the patient could not give informed consent before aneurysm repair and there are no relatives who could be asked to act on behalf of the patient. Although the patient has survived the emergency surgery, the patient remains unable to give informed consent to continued participation in the trial, as required in the schedule shown below.

You are being asked to offer an opinion as to whether the patient would have decided to continue to be followed up within the trial, or withdrawn from the trial. Care will not be compromised if the patient is withdrawn from the trial.

**Follow-up schedule for continued participation in the trial:**

| | **Open surgery** |
|---|---|
| **Clinic visits** | 3 months after operation<br>12 months after operation |
| **Questionnaires** | 3 months after operation<br>12 months after operation |
| **Hospital note review** | Until 5y after operation |

**IMPROVE Trial Contacts:**

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Vascular Surgery Research Group, Imperial College at Charing Cross Hospital
St. Dunstan's Road, London W6 8RP

**Local Contact:** _____

The patient is under no obligation to continue in the study and may withdraw any time without giving a reason. If the patient withdraws from the study, care will not be compromised and they will be offered standard follow-up. After open repair this usually comprises one or two clinic visits post-operatively.

If the patient remains in the trial they will be asked to attend two clinic appointments in the first post-operative year (see schedule). We also seek permission to review the patient's hospital notes for up to 5 years after the operation.

**Summary of the IMPROVE trial**

This patient had a ruptured abdominal aortic aneurysm. This is a condition where the main blood vessel in the tummy has swollen over many years and burst causing extensive bleeding. Many patients with this condition do not survive to reach hospital alive. Of those that reach hospital alive only 50% will survive the operation to repair the aorta and stop the bleeding.

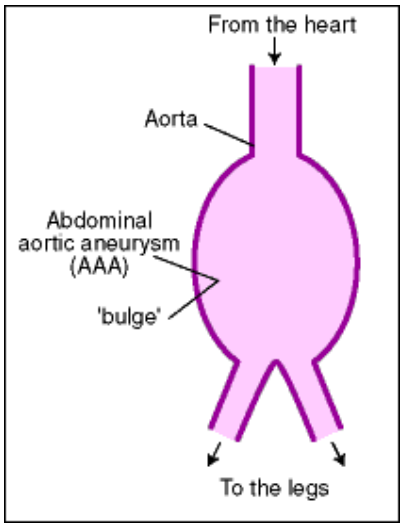
Until recently there was only one way to repair the ruptured aneurysm. This involved major surgery with a large cut in the tummy and replacement of the diseased aorta with a plastic (Polyester) tube (open surgery) and only half the patients leave hospital alive. Recent technical advances have made it possible to re-line the ruptured aorta using a stent introduced through two small cuts in the groin (endovascular repair) and it is possible that a greater proportion of patients will leave hospital alive. However, at present we do not know which of the treatments is best for people with ruptured aneurysm.

This patient has been enrolled in a trial involving a number of specialist UK hospitals. The trial compares the two techniques for repair of ruptured abdominal aortic aneurysm in many patients. When this patient was admitted to hospital we did not know whether they would receive endovascular or open repair. The patient had an open repair, and we shall advise the GP of this when the patient leaves hospital.

**What is an AAA?**

An aneurysm is a localised, balloon-like stretching of a weakened artery (blood vessel) wall. Although this can happen to any artery in the body, the most commonly affected vessel is the aorta which is the main central artery in the body. It carries blood from the heart down through the chest and abdomen (stomach) and branches

out to all of the body's major organs. A normal aorta is about 1.5-2.5cm (¾ -1 inch) in diameter.




This diagram shows what your aorta looks like with an aneurysm

Aortic aneurysms are often silent with no obvious symptoms. However, about 1 in 4 patients will experience some symptoms such as tenderness in the chest or stomach area, back pain and/or reduced blood flow to their legs. When an abdominal aortic aneurysm increases in size, and particularly when the diameter is 5.5cm (2 ¼ inches) or greater, there is an increasing risk that the artery wall will leak or even burst. This is known as a "rupture" and leads to dangerous bleeding inside the body.

**Ruptured abdominal aortic aneurysm**

A ruptured aneurysm can be associated with severe pain in the stomach or back area, a rapid heart beat, a pulsing sensation in the stomach and skin feeling "cold and sweaty". Only 2 in 10 people survive an aortic aneurysm rupture and just half of all patients manage to get to a hospital at all. About 12,000 people die from ruptured aneurysms in U.K. every year.

**What causes an abdominal aortic aneurysm?**

Aortic aneurysm can occur when the wall of the aorta has been damaged and weakened by one or more of the possible risk factors such as:

• Smoking
• High blood pressure
• Atherosclerosis - build up of fatty deposits leading to deterioration of the artery wall and loss of elasticity
• Inherited aortic wall weakness / family history
• Age

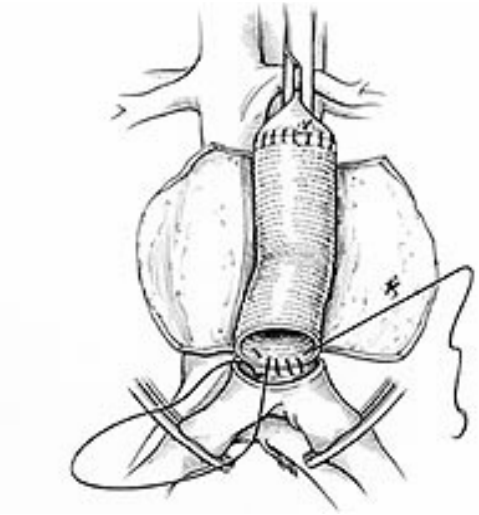
Infection and injury are also thought to be possible causes for the artery to expand and form an aneurysm.

**Who gets an abdominal aortic aneurysm?**

Aneurysms occur in approximately 1 in 20 men over the age of 65. They are four to five times more common in men than women. There is also an increased risk of a younger man developing an aneurysm if his father, mother or brother has been diagnosed with the condition.

**What is open surgical repair of an abdominal aortic aneurysm?**

This method of aortic aneurysm repair was developed in the mid-1950s. It is a major operation carried out by Vascular Surgeons in an operating theatre and the patient is given a general anaesthetic. A large cut, starting from just below the chest, is usually made lengthways to the abdomen to expose the aorta and clamps are temporarily placed above and below the aneurysm to shut off the blood flow through the vessel and stop the bleeding. Blood flow to the legs is interrupted while the aorta is clamped. This is not usually a problem as heparin is given to prevent the blood from clotting. The aneurysm is cut open and any blood clot or debris is removed from within it. The artificial graft is then sewn onto the blood vessel at the top and bottom of the aneurysm sac where there is no disease, so that it lies within what was the inside of the aneurysm. When the clamps have been removed and blood flow is re-established without any leaks, the wall of the aneurysm is closed over the graft to protect it. Patients will require a blood transfusion during or after the operation to replace several litres which is typically lost during the procedure although this amount may be much greater in difficult or prolonged operations. The surgery usually takes 2 – 3 hours to complete.



This diagram shows an artificial graft being sewn into the artery inside the aneurysm.

***Hospital stay, recovery time and follow-up**:* Most patients will spend several days or longer after an open repair in an Intensive Care Unit (ICU). They will remain in hospital for a total of 7-10 days or more. Full recovery from a major operation of this type can typically take up to 3-6 months. Long term complications after a successful repair are comparatively rare. The grafts are known to last for 20-30 years and so patients do not need further follow-up appointments beyond three months after a successful repair.

**What are the risks and complications associated with open surgical repair?**

Ruptured aortic aneurysm is an immediately life threatening procedure. Without an operation patients do not survive. Consequently operations to save patients lives are associated with major complications, which include heart attack, stroke, kidney failure, chest and wound problems.

**Will the patient's part in this study be kept confidential?**

Some parts of the patient's medical records and the data collected for the study will be looked at by authorised persons from the team organising the research. They may also be looked at by representatives of regulatory authorities and by authorised people to check that the study is being carried out correctly. The NHS Information Centre and NHS Central Register may use this information to help contact the patient and provide information about the patient's health status. All will have a duty of confidentiality to the patient as a research participant and we will do our best to meet this duty.

**Who has reviewed this study (the IMPROVE trial)?**

The Health Technology Assessment programme of the National Institute for Health Research is supporting this study. The study has received a favourable ethical opinion for conduct by the Berkshire Research Ethics Committee and the Scotland A Research Ethics Committee.

**What if something goes wrong?**

Imperial College London (the trial Sponsor) holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Chief Investigator *(Professor Janet T. Powell) and local Principal Investigator, whose contact details have been provided on page 1.* The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College Joint Research Office .

**Further information**

If you have any questions about the study, please speak to the study nurse or doctor, who will be able to provide you with up to date information about the procedures involved

If you would like to read more about this trial you can contact:
Name:
Telephone:
Email:
Study website: www.improvetrial.org
www.clinicaltrials.gov
Trial ID:NTC00746122

**Must be printed on Trust headed paper, with name and contact details of the local Principal Investigator**

# Information for Consultees for patients having had Endovascular Repair

## Your role as a Consultee

You are acting on behalf of a patient enrolled in a trial of emergency repair of abdominal aortic aneurysm, where enrolment was under the authority of the Mental Capacity Act, as recommended by Berkshire Research Ethics Committee. This happened because the patient could not give informed consent before aneurysm repair and there are no relatives who could be asked to act on behalf of the patient. Although the patient has survived the emergency surgery, the patient remains unable to give informed consent to continued participation in the trial, as required in the schedule shown below.

You are being asked to offer an opinion as to whether the patient would have decided to continue to be followed up within the trial, or withdrawn from the trial. Care will not be compromised if the patient is withdrawn from the trial.

**Follow-up schedule for continued participation in the trial:**

| | **Endovascular repair** |
|---|---|
| **Clinic visit*** | 3 months after operation<br>12 months after operation |
| **CT scan*** | 3 months after operation<br>12 months operation |
| **Questionnaire** | 3 months after operation<br>12 months after operation |
| **Hospital notes review** | Up to 5 years after operation |
| **Health status check** | Beyond 12 months after operation |

*similar to routine care

**IMPROVE Trial Contacts:**

**Trial Chief Investigator:** Professor Janet T Powell
E-mail: j.powell@imperial.ac.uk
Tel: 020 8846 7312
Fax: 020 8846 7330

**Trial Manager:** Dr Pinar Ulug
E-mail: p.ulug@imperial.ac.uk
Tel: 020 8383 3651
Fax: 020 8846 7318

Vascular Surgery Research Group, Imperial College at Charing Cross Hospital
St. Dunstan's Road, London W6 8RP

**Local Contact:** _____

The patient is under no obligation to continue in the study and may withdraw any time without giving a reason. If the patient withdraws from the study, care will not be compromised and they will be offered standard follow-up. After open repair this usually comprises one or two clinic visits post-operatively.

If the patient remains in the trial they will be asked to attend two clinic appointments in the first post-operative year (see schedule). We also seek permission to review the patient's hospital notes for up to 5 years after the operation.

**Summary of the IMPROVE trial**

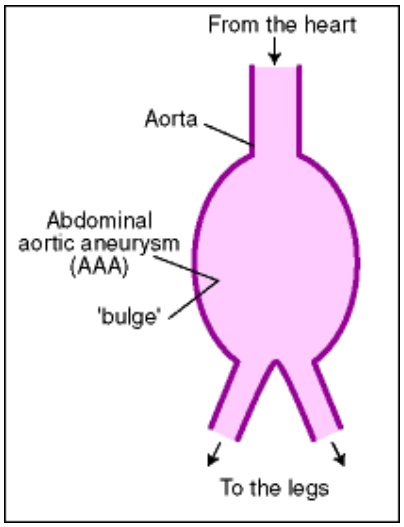
This patient had a ruptured abdominal aortic aneurysm. This is a condition where the main blood vessel in the tummy has swollen over many years and burst causing extensive bleeding. Many patients with this condition do not survive to reach hospital alive. Of those that reach hospital alive only 50% will survive the operation to repair the aorta and stop the bleeding.

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) and only half the patients leave hospital alive. Recent technical advances have made it possible to re-line the ruptured aorta using a stent introduced through two small cuts in the groin (endovascular repair) and it is possible that a greater proportion of patients will leave hospital alive. However, at present we do not know which of the treatments is best for people with ruptured aneurysm.

This patient has been enrolled in a trial involving a number of specialist UK hospitals. The trial compares the two techniques for repair of ruptured abdominal aortic aneurysm in many patients. When this patient was admitted to hospital we did not know whether they would receive endovascular or open repair. The patient had an endovascular repair, and we shall advise the GP of this when the patient leaves hospital.

**What is an AAA?**

An aneurysm is a localised, balloon-like stretching of a weakened artery (blood vessel) wall. Although this can happen to any artery in the body, the most commonly affected vessel is the aorta which is the main central artery in the body. It carries blood from the heart down through the chest and abdomen (stomach) and branches out to all of the body's major organs. A normal aorta is about 1.5-2.5cm (¾ -1 inch) in diameter.




This diagram shows what your aorta looks like with an aneurysm

Aortic aneurysms are often silent with no obvious symptoms. However, about 1 in 4 patients will experience some symptoms such as tenderness in the chest or stomach area, back pain and/or reduced blood flow to their legs. When an abdominal aortic aneurysm increases in size, and particularly when the diameter is 5.5cm (2 ¼ inches) or greater, there is an increasing risk that the artery wall will leak or even burst. This is known as a "rupture" and leads to dangerous bleeding inside the body.

**Ruptured abdominal aortic aneurysm**

A ruptured aneurysm can be associated with severe pain in the stomach or back area, a rapid heart beat, a pulsing sensation in the stomach and skin feeling "cold and sweaty". Only 2 in 10 people survive an aortic aneurysm rupture and just half of all patients manage to get to a hospital at all. About 12,000 people die from ruptured aneurysms in U.K. every year.

**What causes an abdominal aortic aneurysm?**

Aortic aneurysm can occur when the wall of the aorta has been damaged and weakened by one or more of the possible risk factors such as:

• Smoking

• High blood pressure
• Atherosclerosis - build up of fatty deposits leading to deterioration of the artery wall and loss of elasticity
• Inherited aortic wall weakness / family history
• Age

Infection and injury are also thought to be possible causes for the artery to expand and form an aneurysm.

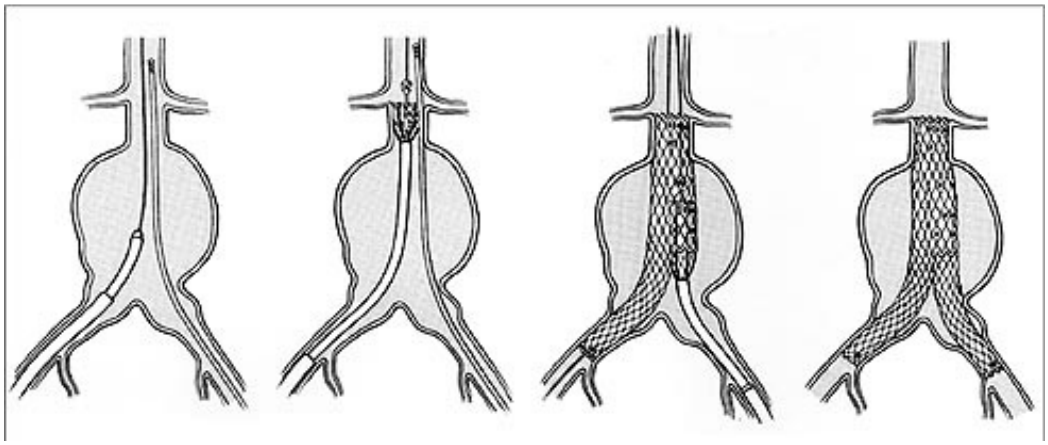
**Who gets an abdominal aortic aneurysm?**

Aneurysms occur in approximately 1 in 20 men over the age of 65. They are four to five times more common in men than women. There is also an increased risk of a younger man developing an aneurysm if his father, mother or brother has been diagnosed with the condition.

**What is Endovascular stent-graft repair (EVAR) of an abdominal aortic aneurysm?**

EVAR was developed in the early 1990s by surgeons in the Ukraine and Argentina as a less invasive alternative to open aneurysm repair. The procedure is carried out by a specialised team sometimes including both Vascular Surgeons and Interventional Radiologists. As the patient can be given a local anaesthetic instead of a general anaesthetic, the repair can be carried out either in an operating theatre or in an angiography suite in the Radiology Department.

A small cut is made in each groin to allow access to the femoral arteries and catheters are passed through these arteries into the aneurysm. Using X-ray for guidance, the synthetic endovascular stent-graft is passed through the catheters up to the aneurysm and positioned at the top and bottom of the diseased part of the aorta. The main body of the graft is located in the aorta and the legs extend down from the main body into the iliac arteries. The stent-graft is then expanded inside the aneurysm and fastened in place by metal stents to form a new stable channel for blood flow and seals off (excludes) the aneurysm. The graft strengthens the weakened aorta wall and prevents the aneurysm from rupturing.



This diagram shows the catheter being passed up through the aneurysm and then the stent –graft being passed up through the catheters. It is positioned at the top and bottom parts of the aneurysm and expanded to fasten in place.

There may be a need for additional endovascular or surgical procedures before, during or after the main procedure in order to complete the EVAR deployment successfully. These may include stents in the iliac arteries, “blocking off” of selected arteries or bypass grafting. Endovascular repair usually takes 2 to 3 hours to complete. During this period the correct positioning of the graft requires further X-ray studies and hence exposure to further radiation.

Most patients will spend time in a High Dependency or Intensive Care unit and will remain in hospital for a total of 4-6 days. It is possible to return to normal activity within 4 to 6 weeks. Because the long term results of endovascular repair have not yet been established, it is required that patients attend routine follow-up visits at the hospital for the rest of their life. They also need to have a CT scan every year to monitor the status of both the old aneurysm and the endovascular stent-graft.

**What are the risks and complications with treatment?**

Ruptured aortic aneurysm is an immediately life threatening procedure. Without an operation patients do not survive. Consequently operations to save patients lives are associated with major complications, which include heart attack, stroke, kidney failure, or chest problems, and can be fatal. In a minority of cases, there may be a small amount of new bleeding or the new graft in your aorta may move slightly and threaten the integrity of the repair.

**What is a Computed Tomography (CT) scan?**

This permits your doctors to see how well the new graft in the patient's aorta is working. In order to obtain a CT scan, the patient has to lie flat on his / her back in the CT scanner and extend both arms above the head. The scanner reviews the patient's body and breaks it down into a series of "slices"; the thickness of which can be chosen at the beginning of the scan. These "slices" are then used to build a picture of the inside of the body and the thinner the slices, the greater the amount of detail and information that can be obtained. This will allow the doctors to check that there is no renewed bleeding and that the graft is staying in its original position. The CT scan will expose the patient to some radiation, but this radiation is unlikely to increase the risk of developing cancer.

**Will the patient's part in this study be kept confidential?**

Some parts of the patient's medical records and the data collected for the study will be looked at by authorised persons from the team organising the research. They may also be looked at by representatives of regulatory authorities and by authorised people to check that the study is being carried out correctly. The NHS Information Centre and NHS Central Register may use this information to help contact the patient and provide information about the patient's health status. All will have a duty of confidentiality to the patient as a research participant and we will do our best to meet this duty.

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should immediately inform the Chief Investigator *(Professor Janet T. Powell) and local Principal Investigator, whose contact details have been provided on page 1.* The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College Joint Research Office .

**Further information**

If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the procedures involved.

If you would like to read more about this trial you can contact:
Name:
Telephone/ Email:
Study website: www.improvetrial.org
ClinicalTrials.gov Identifier: NTC00746122 www.clinicaltrials.gov

**Post-operative consultee assent form**

**Must be printed on Trust headed paper, with name and contact details of the local Principal Investigator**

IMPROVE trial

**I**mmediate **M**anagement of the **P**atient with **R**upture:
**O**pen **V**ersus **E**ndovascular repair

Ethics Ref No: 08/H0505/173

**Patient ID:** ☐☐☐☐

# POST-OPERATIVE ASSENT FORM
## for England, Wales and Northern Ireland

**The post-operative information sheet dated 5th March 2010** (version 4.1) **has been read by:**

**……**
*<insert name and underline status of person: relative/carer/consultee>*

**They have agreed to the continued participation of**

**…… in the IMPROVE Trial.**
*<insert name of patient>*

**They have also agreed to the personal data of ……**
*<insert name of patient>*
**being kept for up to 5 years. Further information about their health status may be obtained from NHS Information Centre and NHS Central Register.**

**Signed** **Date**
*(relative/carer/consultee)*

**Signature of person taking consent** **Date**

**Title/Name:**

**When completed, one copy to be kept in medical notes, one copy for relative/carer/consultee, one copy for investigator site file.**

## Information sheets and consent forms: SCOTLAND

**Pre-operative patient information sheet and consent form**

**Must be printed on Trust headed paper, with name and contact details of the lead clinician**

IMPROVE trial

**I**mmediate **M**anagement of the **P**atient with **R**upture:
**O**pen **V**ersus **E**ndovascular repair

Ethics Ref No: 08/MRE00/90

## The following information sheet is to be read to the patient in Scotland:

You have a life-threatening condition where a major blood vessel has burst in your tummy. You need major surgery (an operation) on your tummy to repair the blood vessel and try to save your life.

*Do you want an operation to try and save your life?*
*Yes.....(signature or mark)*
*No.....(signature or mark)*

There are two methods of doing this operation. The standard method involves cutting open your tummy and replacing the burst blood vessel. The second is a new 'keyhole' technique that involves re-lining the bleeding blood vessel through the artery in your groin: this requires a special X-ray scan first and may lead to a slight delay with this treatment.

We do not know which treatment is best. So, we would like your permission to enter you into a trial where we choose at random which operation you have.

The urgency of the situation means that we will discuss in detail what has happened after your operation.

You are under no obligation to take part in this study. If you decline, your care will not be compromised and you probably will have the standard open operation rather than the new treatment.

**IMPROVE Trial Contacts:**

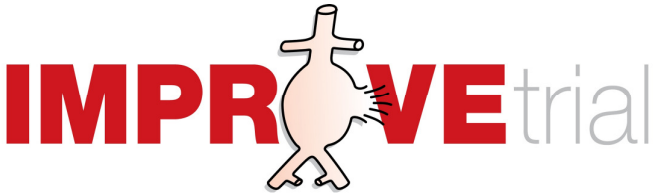
**Trial Chief Investigator:** Professor Janet T Powell
E-mail: j.powell@imperial.ac.uk
Tel: 020 3311 7312 Fax: 020 3311 7330

**Trial Manager:** Dr Pinar Ulug
E-mail: p.ulug@imperial.ac.uk
Tel: 020 3313 3651 Fax: 020 3311 7318

Vascular Surgery Research Group, Imperial College London at Charing Cross Hospital
St. Dunstan's Road, London W6 8RP

**IMPROVE Scotland** **Patient ID** ☐☐☐☐

**Ethics Ref No: 08/MRE00/90**




**I**mmediate **M**anagement of the **P**atient with **R**uptured aneurysm:
**O**pen **V**ersus **E**ndovascular repair

# CONSENT FORM FOR SCOTLAND

**I, ……., have read**
*<insert name of person taking consent>*

**the statement overleaf to ……**
*<insert name and underline status of person **(patient/relative/welfare guardian)** giving consent>*

**Verbal / written consent has been given for ……**
*< Insert name of patient>*

**to be entered into the IMPROVE trial.**

**Signed** **Date**
*(patient/relative/welfare guardian)*

**Signature of person taking consent** **Date**

**Title/Name:**

**IMPROVE Trial Contacts:**

**Trial Chief Investigator:** Professor Janet T Powell
E-mail: j.powell@imperial.ac.uk
Tel: 020 8846 7312 Fax: 020 8846 7330

**Trial Manager:** Dr Pinar Ulug
E-mail: p.ulug@imperial.ac.uk
Tel: 020 8383 3651 Fax: 020 8846 7318

Vascular Surgery Research Group, Imperial College London at Charing Cross Hospital
St. Dunstan's Road, London W6 8RP

**Local Hospital:** _____
**Local Contact:** _____

**Post-operative patient information sheets after open surgery and endovascular repair**

**Must be printed on Trust headed paper, with name and contact details of the local Principal Investigator**

IMPROVE trial

**I**mmediate **M**anagement of **P**atients with **R**uptured aneurysm:
**O**pen **V**ersus **E**ndovascular repair

Ethics Ref No: 08/MRE00/90

# Post-operative Patient Information after Open Surgery

## Summary

You have suffered a ruptured abdominal aortic aneurysm. This is a condition where the main blood vessel in your tummy has swollen over many years and burst causing extensive bleeding. Many patients with your condition do not survive to reach hospital alive. Of those that reach hospital alive only 50% will survive the operation to repair the aorta and stop the bleeding.

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). Recent technical advances have made it possible to re-line the ruptured aorta using a stent introduced through two small cuts in the groin (endovascular repair). However, at present we do not know which of the treatments is best for people with your condition.

You have been enrolled in a trial involving a number of specialist UK hospitals. The trial compares the two techniques for repair of ruptured abdominal aortic aneurysm in many patients. When you were admitted to hospital you consented to receive either open surgery or endovascular repair. The treatment was randomly allocated so we did not know which treatment you were to receive until you entered the trial. You received an open repair, and we shall advise your GP of this when you leave hospital.

**IMPROVE Trial Contacts:**

**Trial Chief Investigator:** Professor Janet T Powell
E-mail: j.powell@imperial.ac.uk
Tel: 020 8846 7312
Fax: 020 8846 7330

**Trial Manager:** Dr Pinar Ulug
E-mail: p.ulug@imperial.ac.uk
Tel: 020 8383 3651
Fax: 020 8846 7318

Vascular Surgery Research Group, Imperial College at Charing Cross Hospital
St. Dunstan's Road, London W6 8RP

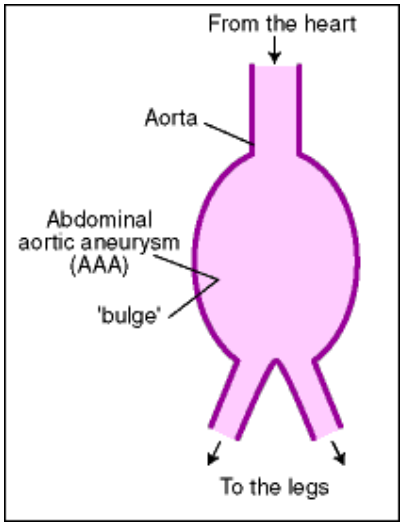
**Local Contact:** _____

You are under no obligation to continue in the study and you may withdraw any time without giving a reason. If you withdraw from the study, your care will not be compromised and you will be offered standard follow-up. In your case this usually comprises one or two clinic visits post-operatively.

If you wish to remain in the trial you will be asked to attend two clinic appointments in the first post-operative year and will be required to reply to two questionnaires (see schedule). We also shall ask for your permission to review your hospital notes for up to 5 years after your operation.

**What is an AAA?**

An aneurysm is a localised, balloon-like stretching of a weakened artery (blood vessel) wall. Although this can happen to any artery in the body, the most commonly affected vessel is the aorta which is the main central artery in the body. It carries blood from the heart down through the chest and abdomen (stomach) and branches out to all of the body's major organs. A normal aorta is about 1.5-2.5cm (¾ -1 inch) in diameter.




This diagram shows what your aorta looks like with an aneurysm

Aortic aneurysms are often silent with no obvious symptoms. However, about 1 in 4 patients will experience some symptoms such as tenderness in the chest or stomach area, back pain and/or reduced blood flow to their legs. When an abdominal aortic aneurysm increases in size, and particularly when the diameter is 5.5cm (2 ¼ inches) or greater, there is an increasing risk that the artery wall will leak or even burst. This is known as a "rupture" and leads to dangerous bleeding inside the body.

**Ruptured abdominal aortic aneurysm**

A ruptured aneurysm can be associated with severe pain in the stomach or back area, a rapid heart beat, a pulsing sensation in the stomach and skin feeling “cold and sweaty”. Only 2 in 10 people survive an aortic aneurysm rupture and just half of all patients manage to get to a hospital at all. About 12 000 people die from ruptured aneurysms in U.K. every year.

**What causes an abdominal aortic aneurysm?**

Aortic aneurysm can occur when the wall of the aorta has been damaged and weakened by one or more of the possible risk factors such as:

- Smoking
- High blood pressure
- Atherosclerosis - build up of fatty deposits leading to deterioration of the artery wall and loss of elasticity
- Inherited aortic wall weakness / family history
- Age

Infection and injury are also thought to be possible causes for the artery to expand and form an aneurysm.

**Who gets an abdominal aortic aneurysm?**

Aneurysms occur in approximately 1 in 20 men over the age of 65. They are four to five times more common in men than women. There is also an increased risk of a younger man developing an aneurysm if his father, mother or brother has been diagnosed with the condition.

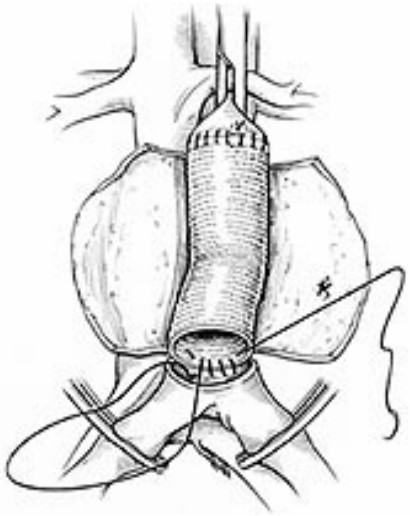
**How is abdominal aortic aneurysm diagnosed?**

As an aneurysm is often symptom free, it is frequently diagnosed by chance when a patient is being examined for another problem or undergoing an x-ray or ultrasound scan for a different reason. Alternatively, a patient may visit their doctor due to stomach or back pain which needs to be investigated. An ultrasound scan is a very good way to tell if there is an aneurysm present and how large it is. This is a quick and painless procedure, which is commonly used for scanning pregnant women, where a hand-held scanning device is passed over the skin on the stomach using special gel. The resulting sound waves are used to build pictures of the internal organs which can be used to diagnose and follow the changes in size of an aneurysm. If an aneurysm is suspected, a doctor or hospital consultant will refer the patient to hospital for an ultrasound scan. An alternative method for the detection of aneurysms is called a CT scan (computerised tomography). This

involves being placed inside a sophisticated X-ray scanner. A CT scan is the best way to confirm the aneurysm has ruptured.

**What is open surgical repair of an abdominal aortic aneurysm?**

This method of aortic aneurysm repair was developed in the mid-1950s. It is a major operation carried out by Vascular Surgeons in an operating theatre and the patient is given a general anaesthetic. A large cut, starting from just below the chest, is usually made lengthways to the abdomen to expose the aorta and clamps are temporarily placed above and below the aneurysm to shut off the blood flow through the vessel and stop the bleeding. Blood flow to the legs is interrupted while the aorta is clamped. This is not usually a problem as heparin is given to prevent the blood from clotting. The aneurysm is cut open and any blood clot or debris is removed from within it. The artificial graft is then sewn onto the blood vessel at the top and bottom of the aneurysm sac where there is no disease, so that it lies within what was the inside of the aneurysm. When the clamps have been removed and blood flow is re-established without any leaks, the wall of the aneurysm is closed over the graft to protect it. Patients will require a blood transfusion during or after the operation to replace several litres which is typically lost during the procedure although this amount may be much greater in difficult or prolonged operations. The surgery usually takes 2 – 3 hours to complete.



This diagram shows an artificial graft being sewn into the artery inside the aneurysm.

**Hospital stay, recovery time and follow-up:**

Most patients will spend several days or longer after an open repair in an Intensive Care Unit (ICU). They will remain in hospital for a total of 7-10 days or more. Full recovery from a major operation of this type can typically take up to 3-6 months. Long term complications after a successful repair are comparatively rare. The grafts are

known to last for 20-30 years and so patients do not need further follow-up appointments beyond twelve months after a successful repair for aneurysm rupture.

**What are the risks and complications associated with open surgical repair?**

Ruptured aortic aneurysm is an immediately life threatening procedure. Without an operation patients do not survive. Consequently operations to save patients lives are associated with major complications, which include heart attack, stroke, kidney failure, chest and wound problems.

**Follow-up schedule for continued participation in the trial:**

| | **Open surgery** |
|---|---|
| **Clinic visits** | 3 months after operation<br>12 months after operation |
| **Questionnaires** | 3 months after operation<br>12 months after operation |
| **Hospital note review** | Until 5y after operation |

**Will my taking part in this study be kept confidential?**

If you agree to continue in this trial, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the team organising the research. They may also be looked at by representatives of regulatory authorities and by authorised people to check that the study is being carried out correctly. The NHS Information Centre and NHS Central Register may use this information to help contact you and provide information about your health status. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

**Who has reviewed this study (the IMPROVE trial)?**

The Health Technology Assessment programme of the National Institute for Health Research is supporting this study. The study has received a favourable ethical opinion for conduct by the Berkshire Research Ethics Committee and the Scotland A Research Ethics Committee.

**What if something goes wrong?**

Imperial College London (the trial Sponsor) holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Chief Investigator *(Professor Janet T. Powell) and local Principal Investigator, whose contact details have been provided on page 1.* The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College Joint Research Office.

**Further information**

If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the procedures involved.

If you would like to read more about this trial you can contact:

Name:

Telephone/ Email:

Study website: www.improvetrial.org

ClinicalTrials.gov Identifier: NTC00746122 www.clinicaltrials.gov

**Must be printed on Trust headed paper, with name and contact details of the local Principal Investigator**

IMPROVE trial

**I**mmediate **M**anagement of **P**atients with **R**uptured
**O**pen **V**ersus **E**ndovascular repair

Ethics Ref No: 08/MRE00/90

# Post-operative Patient Information after Endovascular Repair

## Summary

You have suffered a ruptured abdominal aortic aneurysm. This is a condition where the main blood vessel in your tummy has swollen over many years and burst causing extensive bleeding. Many patients with your condition do not survive to reach hospital alive. Of those that reach hospital alive only 50% will survive the operation to repair the aorta and stop the bleeding.

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). Recent technical advances have made it possible to re-line the ruptured aorta using a stent introduced through two small cuts in the groin (endovascular repair). However, at present we do not know which of the treatments is best for people with your condition.

You have been enrolled in a trial involving a number of specialist UK hospitals. The trial compares the two techniques for repair of ruptured abdominal aortic aneurysm in many patients. When you were admitted to hospital you consented to receive either open surgery or endovascular repair. The treatment was randomly allocated so we did not know which treatment you were to receive until you entered the trial. You received an endovascular repair, and we shall advise your GP of this when you leave hospital.

**IMPROVE Trial Contacts:**

**Trial Chief Investigator:** Professor Janet T Powell
E-mail: j.powell@imperial.ac.uk
Tel: 020 8846 7312
Fax: 020 8846 7330

**Trial Manager:** Dr Pinar Ulug
E-mail: p.ulug@imperial.ac.uk
Tel: 020 8383 3651
Fax: 020 8846 7318

Vascular Surgery Research Group, Imperial College at Charing Cross Hospital
St. Dunstan's Road, London W6 8RP

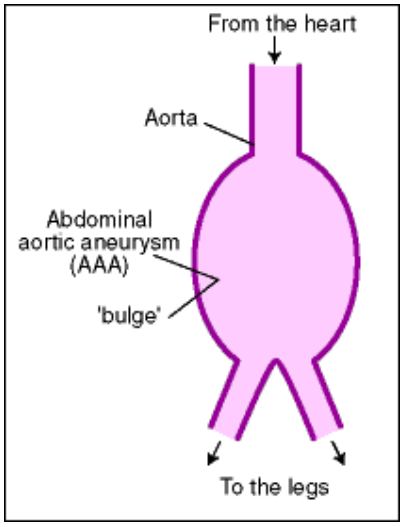
**Local Contact:** _____

You are under no obligation to continue in the study and you may withdraw any time without giving a reason. If you withdraw from the study, your care will not be compromised and you will be offered standard follow-up. Most surgeons suggest at least yearly scans and clinic visits following endovascular repair to ensure it continues to work effectively.

If you wish to remain in the trial you will be asked to attend two clinic appointments and 2 CT scans in the first post-operative year and will be required to reply to two questionnaires (see schedule).

**What is an AAA?**

An aneurysm is a localised, balloon-like stretching of a weakened artery (blood vessel) wall. Although this can happen to any artery in the body, the most commonly affected vessel is the aorta which is the main central artery in the body. It carries blood from the heart down through the chest and abdomen (stomach) and branches out to all of the body's major organs. A normal aorta is about 1.5-2.5cm (¾ -1 inch) in diameter.




This diagram shows what your aorta looks like with an aneurysm

Aortic aneurysms are often silent with no obvious symptoms. However, about 1 in 4 patients will experience some symptoms such as tenderness in the chest or stomach area, back pain and/or reduced blood flow to their legs. When an abdominal aortic aneurysm increases in size, and particularly when the diameter is 5.5cm (2 ¼ inches) or greater, there is an increasing risk that the artery wall will leak or even burst. This is known as a "rupture" and leads to dangerous bleeding inside the body.

**Ruptured abdominal aortic aneurysm**

A ruptured aneurysm can be associated with severe pain in the stomach or back area, a rapid heart beat, a pulsing sensation in the stomach and skin feeling “cold and sweaty”. Only 2 in 10 people survive an aortic aneurysm rupture and just half of all patients manage to get to a hospital at all. About 12 000 people die from ruptured aneurysms in U.K. every year.

**What causes an abdominal aortic aneurysm?**

Aortic aneurysm can occur when the wall of the aorta has been damaged and weakened by one or more of the possible risk factors such as:

- Smoking
- High blood pressure
- Atherosclerosis - build up of fatty deposits leading to deterioration of the artery wall and loss of elasticity
- Inherited aortic wall weakness / family history
- Age

Infection and injury are also thought to be possible causes for the artery to expand and form an aneurysm.

**Who gets an abdominal aortic aneurysm?**

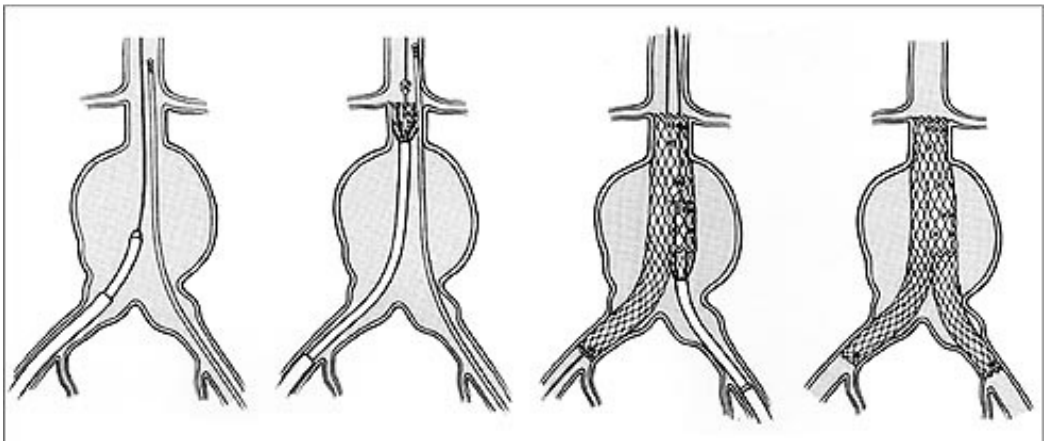
Aneurysms occur in approximately 1 in 20 men over the age of 65. They are four to five times more common in men than women. There is also an increased risk of a younger man developing an aneurysm if his father, mother or brother has been diagnosed with the condition.

**What is Endovascular stent-graft repair (EVAR) of an abdominal aortic aneurysm?**

EVAR was developed in the early 1990s by surgeons in the Ukraine and Argentina as a less invasive alternative to open aneurysm repair. The procedure is carried out by a specialised team sometimes including both Vascular Surgeons and Interventional Radiologists. As the patient can be given a local anaesthetic instead of a general anaesthetic, the repair can be carried out either in an operating theatre or in an angiography suite in the Radiology Department.

A small cut is made in each groin to allow access to the femoral arteries and catheters are passed through these arteries into the aneurysm. Using X-ray for guidance, the synthetic endovascular stent-graft is passed through the catheters up to the aneurysm and positioned at the top and bottom of the diseased part of the

aorta. The main body of the graft is located in the aorta and the legs extend down from the main body into the iliac arteries. The stent-graft is then expanded inside the aneurysm and fastened in place by metal stents to form a new stable channel for blood flow and seals off (excludes) the aneurysm. The graft strengthens the weakened aorta wall and prevents the aneurysm from rupturing.



This diagram shows the catheter being passed up through the aneurysm and then the stent –graft being passed up through the catheters. It is positioned at the top and bottom parts of the aneurysm and expanded to fasten in place.

There may be a need for additional endovascular or surgical procedures before, during or after the main procedure in order to complete the EVAR deployment successfully. These may include stents in the iliac arteries, “blocking off” of selected arteries or bypass grafting. Endovascular repair usually takes 2 to 3 hours to complete. During this period the correct positioning of the graft requires further X-ray studies and hence exposure to further radiation.

Most patients will spend time in a High Dependency or Intensive Care unit and will remain in hospital for a total of 4-6 days. It is possible to return to normal activity within 4 to 6 weeks. Because the long term results of endovascular repair have not yet been established, it is required that patients attend routine follow-up visits at the hospital for the rest of their life. They also need to have a CT scan every year to monitor the status of both the old aneurysm and the endovascular stent-graft.

**What are the risks and complications with treatment?**

Ruptured aortic aneurysm is an immediately life threatening procedure. Without an operation patients do not survive. Consequently operations to save patients lives are

associated with major complications. These include heart attack, stroke, kidney failure or chest problems, and can be fatal. In a minority of cases, there may be a small amount of new bleeding or the new graft in your aorta may move slightly and threaten the integrity of the repair.

**Computed Tomography (CT) scan**

This permits your doctors to see how well the new graft in your aorta is working. In order to obtain a CT scan, the patient has to lie flat on his / her back in the CT scanner and extend both arms above the head. The scanner reviews the patient's body and breaks it down into a series of "slices"; the thickness of which can be chosen at the beginning of the scan. These "slices" are then used to build a picture of the inside of the body and the thinner the slices, the greater the amount of detail and information that can be obtained. This will allow your doctors to check that there is no renewed bleeding and that the graft is staying in its original position. The CT scan will expose you to some radiation, but this radiation is unlikely to increase your risk of developing cancer.

**Follow-up schedule:**

| | **Endovascular repair** |
|---|---|
| **Clinic visit** | 3 months after operation<br>12 months after operation |
| **CT scan** | 3 months after operation<br>12 months operation |
| **Questionnaire** | 3 months after operation<br>12 months after operation |
| **Hospital notes review** | Up to 5 years after operation |
| **Health status check** | Beyond 12 months |

**Will my taking part in this study be kept confidential?**

If you agree to continue in this trial, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the team organising the research. They may also be looked at by representatives of regulatory authorities and by authorised people to check that the study is being carried out correctly. The NHS Information Centre and

NHS Central Register may use this information to help contact you and provide information about your health status. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

**Who has reviewed this study (the IMPROVE trial)?**

The Health Technology Assessment programme of the National Institute for Health Research is supporting this study. The study has received a favourable ethical opinion for conduct by the Berkshire Research Ethics Committee and the Scotland A Research Ethics Committee.

**What if something goes wrong?**

Imperial College London (the trial Sponsor) holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Chief Investigator *(Professor Janet T. Powell) and local Principal Investigator, whose contact details have been provided on page 1.* The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College Joint Research Office.

**Further information**

If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the procedures involved. If you would like to read more about this trial you can contact:

Name:

Telephone/ Email:

Study website: www.improvetrial.org

ClinicalTrials.gov Identifier: NTC00746122 www.clinicaltrials.gov

**Post-operative information for relatives, carers & welfare guardians after open surgery and endovascular repair**

**Must be printed on Trust headed paper, with name and contact details of the local Principal Investigator**

IMPROVE trial

**I**mmediate **M**anagment of **P**atients with **R**upture:
**O**pen **V**ersus **E**ndovascular repair

Ethics Ref No: 08/MRE00/90

# Post-operative Information for Relatives, Carers & Welfare Guardians after Open Surgery

## Summary

Your relative or dependent has suffered a ruptured abdominal aortic aneurysm. This is a condition where the main blood vessel in the tummy has swollen over many years and burst causing extensive bleeding. Many patients with their condition do not survive to reach hospital alive. Of those that reach hospital alive only 50% will survive the operation to repair the aorta and stop the bleeding.

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). Recent technical advances have made it possible to re-line the ruptured aorta using a stent introduced through two small cuts in the groin (endovascular repair). However, at present we do not know which of the treatments is best for people with this condition.

Your relative or dependent has been enrolled in a trial involving a number of specialist UK hospitals. The trial compares the two techniques for repair of ruptured abdominal aortic aneurysm in many patients. When your relative or dependent were admitted to hospital they received either open surgery or endovascular repair. The treatment was randomly allocated so we did not know which treatment would be received until s/he entered the trial. Your relative or dependent received an open repair, and we shall advise the GP of this when they leave hospital.

**IMPROVE Trial Contacts:**

**Trial Chief Investigator:** Professor Janet T Powell
E-mail: j.powell@imperial.ac.uk
Tel: 020 8846 7312 Fax: 020 8846 7330

**Trial Manager:** Dr Pinar Ulug
E-mail: p.ulug@imperial.ac.uk
Tel: 020 8383 3651 Fax: 020 8846 7318

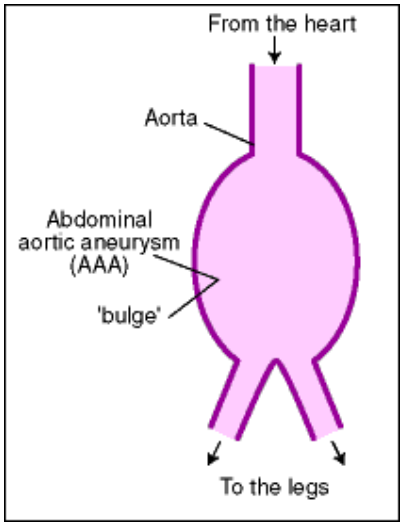
Vascular Surgery Research Group, Imperial College at Charing Cross Hospital
St. Dunstan's Road, London W6 8RP

Your relative or dependent is under no obligation to continue in the study and withdraw any time without giving a reason. If they withdraw from the study, their care will not be compromised and they will be offered standard follow-up. After open repair this usually comprises one or two clinic visits post-operatively.

If s/he wish to remain in the trial they will be asked to attend two clinic appointments in the first post-operative year (see schedule). We also seek permission to review their hospital notes for up to 5 years after the operation.

**What is an AAA?**

An aneurysm is a localised, balloon-like stretching of a weakened artery (blood vessel) wall. Although this can happen to any artery in the body, the most commonly affected vessel is the aorta which is the main central artery in the body. It carries blood from the heart down through the chest and abdomen (stomach) and branches out to all of the body's major organs. A normal aorta is about 1.5-2.5cm (¾ -1 inch) in diameter.




This diagram shows what your aorta looks like with an aneurysm

Aortic aneurysms are often silent with no obvious symptoms. However, about 1 in 4 patients will experience some symptoms such as tenderness in the chest or stomach area, back pain and/or reduced blood flow to their legs. When an abdominal aortic aneurysm increases in size, and particularly when

the diameter is 5.5cm (2 ¼ inches) or greater, there is an increasing risk that the artery wall will leak or even burst. This is known as a “rupture” and leads to dangerous bleeding inside the body.

**Ruptured abdominal aortic aneurysm**

A ruptured aneurysm can be associated with severe pain in the stomach or back area, a rapid heart beat, a pulsing sensation in the stomach and skin feeling “cold and sweaty”. Only 2 in 10 people survive an aortic aneurysm rupture and just half of all patients manage to get to a hospital at all. About 12 000 people die from ruptured aneurysms in U.K. every year.

**What causes an abdominal aortic aneurysm?**

Aortic aneurysm can occur when the wall of the aorta has been damaged and weakened by one or more of the possible risk factors such as:

• Smoking
• High blood pressure
• Atherosclerosis - build up of fatty deposits leading to deterioration of the artery wall and loss of elasticity
• Inherited aortic wall weakness / family history
• Age

Infection and injury are also thought to be possible causes for the artery to expand and form an aneurysm.

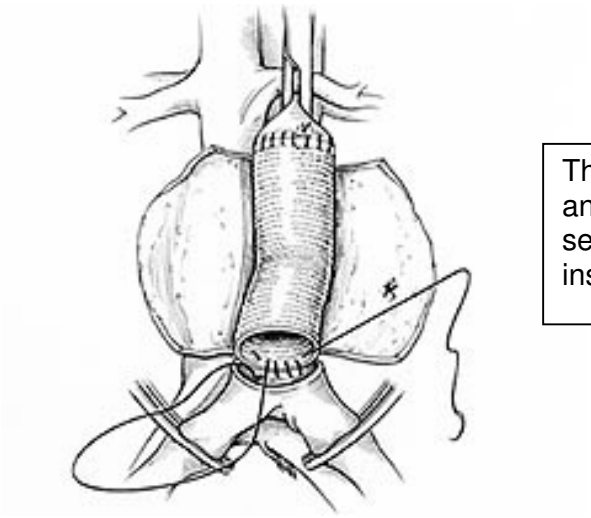
**Who gets an abdominal aortic aneurysm?**

Aneurysms occur in approximately 1 in 20 men over the age of 65. They are four to five times more common in men than women. There is also an increased risk of a younger man developing an aneurysm if his father, mother or brother has been diagnosed with the condition.

**What is open surgical repair of an abdominal aortic aneurysm?**

This method of aortic aneurysm repair was developed in the mid-1950s. It is a major operation carried out by Vascular Surgeons in an operating theatre and the patient is given a general anaesthetic. A large cut, starting from just below the chest, is usually made lengthways to the abdomen to expose the aorta

and clamps are temporarily placed above and below the aneurysm to shut off the blood flow through the vessel and stop the bleeding. Blood flow to the legs is interrupted while the aorta is clamped. This is not usually a problem as heparin is given to prevent the blood from clotting. The aneurysm is cut open and any blood clot or debris is removed from within it. The artificial graft is then sewn onto the blood vessel at the top and bottom of the aneurysm sac where there is no disease, so that it lies within what was the inside of the aneurysm. When the clamps have been removed and blood flow is re-established without any leaks, the wall of the aneurysm is closed over the graft to protect it. Patients will require a blood transfusion during or after the operation to replace several litres which is typically lost during the procedure although this amount may be much greater in difficult or prolonged operations. The surgery usually takes 2 – 3 hours to complete.



This diagram shows an artificial graft being sewn into the artery inside the aneurysm.

*Hospital stay, recovery time and follow-up:* Most patients will spend several days or longer after an open repair in an Intensive Care Unit (ICU). They will remain in hospital for a total of 7-10 days or more. Full recovery from a major operation of this type can typically take up to 3-6 months. Long term complications after a successful repair are comparatively rare. The grafts are known to last for 20-30 years and so patients do not need further follow-up appointments beyond twelve months after a successful repair for aneurysm rupture.

**Risks and complications associated with open surgical repair**

Ruptured aortic aneurysm is an immediately life threatening procedure. Without an operation patients do not survive. Consequently operations to save patients lives are associated with major complications, which include heart attack, stroke, kidney failure, chest and wound problems.

**Follow-up schedule for continued participation in the trial**

| | **Open surgery** |
|---|---|
| **Clinic visits** | 3 months after operation<br>12 months after operation |
| **Hospital note review** | Until 5y after operation |
| **Health status check** | Beyond 12 months after operation |

**Will the patient's part in this study be kept confidential?**

Some parts of the patient's medical records and the data collected for the study will be looked at by authorised persons from the team organising the research. They may also be looked at by representatives of regulatory authorities and by authorised people to check that the study is being carried out correctly. The NHS Information Centre and NHS Central Register may use this information to help contact you and provide information about your health status. All will have a duty of confidentiality to the patient as a research participant and we will do our best to meet this duty.

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If you would like to read more about this trial you can contact:

Name:

Telephone:

Email:

Study website: www.improvetrial.org

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Trial ID:NTC00746122

**Must be printed on Trust headed paper, with name and contact details of the local Principal Investigator**

IMPROVE trial

**I**mmediate **M**anagement of **P**atients with **R**upture
**O**pen **V**ersus **E**ndovascular repair

Ethics Ref No: 08/MRE00/90

# Post-operative Information for Relatives, Carers or Welfare Guardians after Endovascular Repair

## Summary

Your relative or dependent has suffered a ruptured abdominal aortic aneurysm. This is a condition where the main blood vessel in the tummy has swollen over many years and burst causing extensive bleeding. Many patients with their condition do not survive to reach hospital alive. Of those that reach hospital alive only 50% will survive the operation to repair the aorta and stop the bleeding.

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). Recent technical advances have made it possible to re-line the ruptured aorta using a stent introduced through two small cuts in the groin (endovascular repair). However, at present we do not know which of the treatments is best for people with this condition.

Your relative or dependent has been enrolled in a trial involving a number of specialist UK hospitals. The trial compares the two techniques for repair of ruptured abdominal aortic aneurysm in many patients. When they were admitted to hospital they received either open surgery or endovascular repair. The treatment was randomly allocated so we did not know which treatment would be received before the patient entered the trial. Your relative or dependent received an endovascular repair, and we shall advise your GP of this when they leave hospital.

**IMPROVE Trial Contacts:**

**Chief Investigator:** Professor Janet T Powell
E-mail: j.powell@imprial.ac.uk
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**Local Contact:** _____

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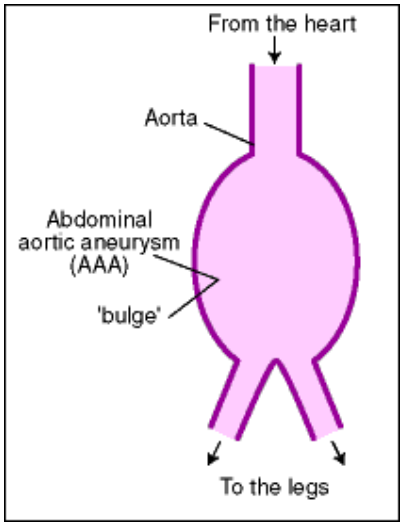
If they remain in the trial they will be asked to attend two clinic appointments and 2 CT scans in the first post-operative year (see schedule).

**What is an AAA?**

An aneurysm is a localised, balloon-like stretching of a weakened artery (blood vessel) wall. Although this can happen to any artery in the body, the most commonly affected vessel is the aorta which is the main central artery in the body. It carries blood from the heart down through the chest and abdomen (stomach) and branches out to all of the body's major organs. A normal aorta is about 1.5-2.5cm (¾ -1 inch) in diameter.




This diagram shows what your aorta looks like with an aneurysm

Aortic aneurysms are often silent with no obvious symptoms. However, about 1 in 4 patients will experience some symptoms such as tenderness in the chest or stomach area, back pain and/or reduced blood flow to their legs. When an abdominal aortic aneurysm increases in size, and particularly when the diameter is 5.5cm (2 ¼ inches) or greater, there is an increasing risk that

the artery wall will leak or even burst. This is known as a “rupture” and leads to dangerous bleeding inside the body.

**Ruptured abdominal aortic aneurysm**

A ruptured aneurysm can be associated with severe pain in the stomach or back area, a rapid heart beat, a pulsing sensation in the stomach and skin feeling “cold and sweaty”. Only 2 in 10 people survive an aortic aneurysm rupture and just half of all patients manage to get to a hospital at all. About 12 000 people die from ruptured aneurysms in U.K. every year.

**What causes an abdominal aortic aneurysm?**

Aortic aneurysm can occur when the wall of the aorta has been damaged and weakened by one or more of the possible risk factors such as:

• Smoking
• High blood pressure
• Atherosclerosis - build up of fatty deposits leading to deterioration of the artery wall and loss of elasticity
• Inherited aortic wall weakness / family history
• Age

Infection and injury are also thought to be possible causes for the artery to expand and form an aneurysm.

**Who gets an abdominal aortic aneurysm?**

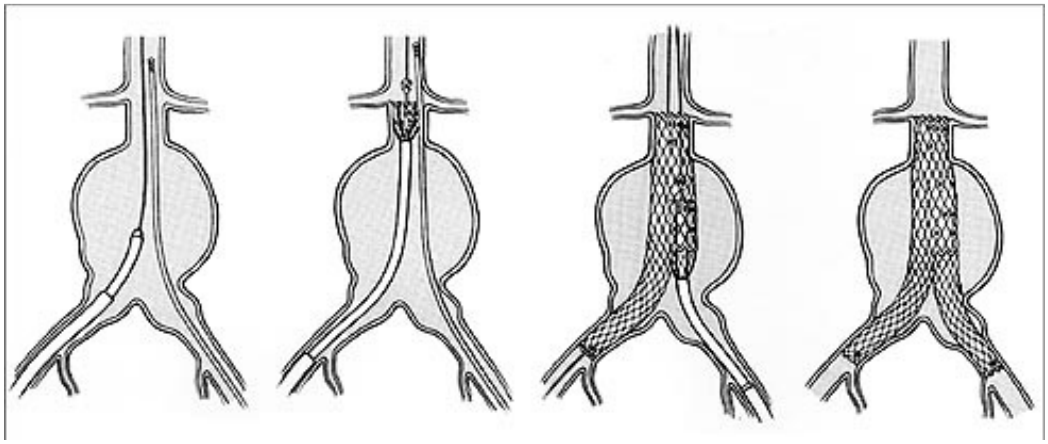
Aneurysms occur in approximately 1 in 20 men over the age of 65. They are four to five times more common in men than women. There is also an increased risk of a younger man developing an aneurysm if his father, mother or brother has been diagnosed with the condition.

**What is endovascular stent-graft repair (EVAR) of an abdominal aortic aneurysm?**

EVAR was developed in the early 1990s by surgeons in the Ukraine and Argentina as a less invasive alternative to open aneurysm repair. The procedure is carried out by a specialised team sometimes including both

Vascular Surgeons and Interventional Radiologists. As the patient can be given a local anaesthetic instead of a general anaesthetic, the repair can be carried out either in an operating theatre or in an angiography suite in the Radiology Department.

A small cut is made in each groin to allow access to the femoral arteries and catheters are passed through these arteries into the aneurysm. Using X-ray for guidance, the synthetic endovascular stent-graft is passed through the catheters up to the aneurysm and positioned at the top and bottom of the diseased part of the aorta. The main body of the graft is located in the aorta and the legs extend down from the main body into the iliac arteries. The stent-graft is then expanded inside the aneurysm and fastened in place by metal stents to form a new stable channel for blood flow and seals off (excludes) the aneurysm. The graft strengthens the weakened aorta wall and prevents the aneurysm from rupturing.



This diagram shows the catheter being passed up through the aneurysm and then the stent –graft being passed up through the catheters. It is positioned at the top and bottom parts of the aneurysm and expanded to fasten in place.

There may be a need for additional endovascular or surgical procedures before, during or after the main procedure in order to complete the EVAR deployment successfully. These may include stents in the iliac arteries, “blocking off” of selected arteries or bypass grafting. Endovascular repair

usually takes 2 to 3 hours to complete. During this period the correct positioning of the graft requires further X-ray studies and hence exposure to further radiation.

Most patients will spend time in a High Dependency or Intensive Care unit and will remain in hospital for a total of 4-6 days. It is possible to return to normal activity within 4 to 6 weeks. Because the long term results of endovascular repair have not yet been established, it is required that patients attend routine follow-up visits at the hospital for the rest of their life. They also need to have a CT scan every year to monitor the status of both the old aneurysm and the endovascular stent-graft.

**What are the risks and complications with treatment?**

Ruptured aortic aneurysm is an immediately life threatening procedure. Without an operation patients do not survive. Consequently operations to save patients lives are associated with major complications. These include heart attack, stroke, kidney failure or chest problems, and can be fatal. In a minority of cases, there may be a small amount of new bleeding or the new graft in your aorta may move slightly and threaten the integrity of the repair.

**Computed Tomography (CT) scan**

This permits the doctors to see how well the new graft in the aorta is working. In order to obtain a CT scan, the patient has to lie flat on his / her back in the CT scanner and extend both arms above the head. The scanner reviews patient's body and breaks it down into a series of "slices"; the thickness of which can be chosen at the beginning of the scan. These "slices" are then used to build a picture of the inside of the body and the thinner the slices, the greater the amount of detail and information that can be obtained. This will allow your doctors to check that there is no renewed bleeding and that the graft is staying in its original position. The CT scan causes some radiation exposure, but this is unlikely to increase the risk of developing cancer.

**Follow-up schedule**

| | **Endovascular repair** |
|---|---|
| **Clinic visit** | 3 months after operation<br>12 months after operation |
| **CT scan** | 3 months after operation<br>12 months operation |
| **Hospital notes review** | Up to 5 years after operation |
| **Health status check** | Beyond 12 months after operation |

**Will the patient's part in this study be kept confidential?**

Some parts of the patient's medical records and the data collected for the study will be looked at by authorised persons from the team organising the research. They may also be looked at by representatives of regulatory authorities and by authorised people to check that the study is being carried out correctly. The NHS Information Centre and NHS Central Register may use this information to help contact you and provide information about your health status. All will have a duty of confidentiality to the patient as a research participant and we will do our best to meet this duty.

**Who has reviewed this study (the IMPROVE trial)?**

The Health Technology Assessment programme of the National Institute for Health Research is supporting this study. The study has received a favourable ethical opinion for conduct by the Berkshire Research Ethics Committee and the Scotland A Research Ethics Committee.

**What if something goes wrong?**

Imperial College London (the trial Sponsor) holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Chief Investigator *(Professor Janet T. Powell) and local Principal Investigator, whose contact details have been provided on page 1.* The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College Joint Research Office.

**Further information**

If you have any questions about the study, please speak to the study nurse or doctor, who will be able to provide you with up to date information about the procedures involved

If you would like to read more about this trial you can contact:

Name:

Telephone:

Email:

Study website: www.improvetrial.org

www.clinicaltrials.gov

Trial ID:NTC00746122

## Post-operative consent form

**Must be printed on Trust headed paper, with name and contact details of the local Principal Investigator**

IMPROVE trial

**I**mmediate **M**anagement of the **P**atient with **R**upture:
**O**pen **V**ersus **E**ndovascular repair

Ethics Ref No: 08/MRE00/90

Patient ID: ☐☐☐☐

# POST-OPERATIVE CONSENT FORM FOR SCOTLAND

**The post-operative information sheet dated 5th March 2010** (version 4.1) **has been read by:**

_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

*<insert name and underline status of person – patient/relative/welfare guardian – giving consent>*

**They have agreed to the continued participation of**

_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ **in the IMPROVE Trial.**

*<insert name of patient>*

**They have also agreed to the personal data of**

_ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ **being kept for up to 5 years.**

*<insert name of patient>*

**Further information about their health status may be obtained from NHS Information Centre and NHS Central Register.**

**Signed** **Date**

*(patient/relative/welfare guardian)*

**Signature of person taking consent** **Date**

**Title/Name:**

**When completed, original to be kept in medical notes, one copy for patient/relative/welfare guardian, one copy for investigator site file**


**IMPROVE Trial Contacts:**

**Trial Chief Investigator:** Professor Janet T Powell
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**Trial Manager:** Dr Pinar Ulug
E-mail: p.ulug@imperial.ac.uk
Tel: 020 8383 3651 Fax: 020 8846 7318

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