Patient information for EVAR trial 2

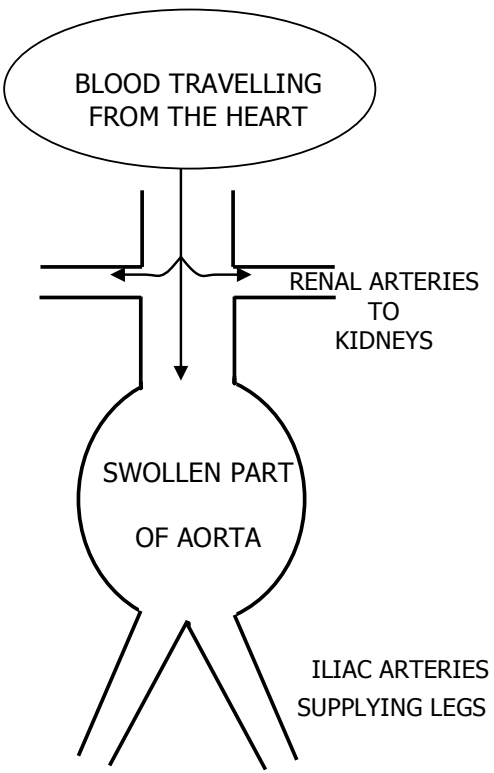
This is intended for patients who have been found to be suitable for the new stent graft aneurysm method but in whom your Doctors are reluctant to recommend the larger conventional open repair operation.

You are being invited to take part in a research study. It is a national study that is expected to involve many patients across the UK. Before you decide if you wish to be involved, it is important for you to understand why the research is being done and what it will entail. Please take time to read the following information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

1. Study title

EndoVascular Aneurysm Repair (EVAR): Trial 2. This trial is for patients who have been found to be suitable for the new stent graft aneurysm method but in whom your Doctors are reluctant to recommend the larger conventional open repair operation.

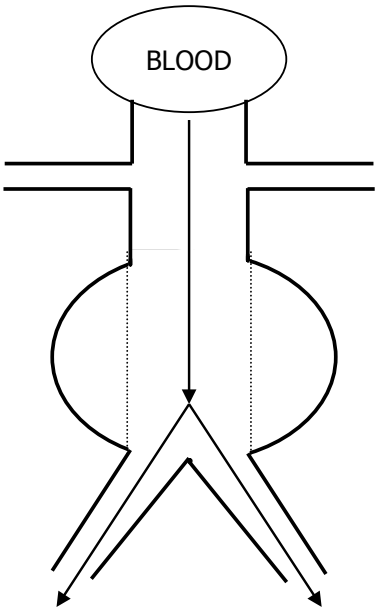
2. What is an Abdominal Aortic Aneurysm?



The abdominal aorta is the main artery that transports blood pumped from your heart to all the parts of your body below the rib cage. For example blood travels from the abdominal aorta to your kidneys along the renal arteries and your legs receive blood from the aorta through the iliac arteries.

You have a condition known as an abdominal aortic aneurysm, where the section of aorta below the renal arteries has swollen outwards like a balloon and is now large enough for your doctor to think that it may rupture. If it did so, it could occur suddenly and might possibly lead to an emergency operation.

3. How are Abdominal Aortic Aneurysms treated?



Investigations have shown that the shape of your aneurysm is such that we could try and use a new stent graft system to strengthen the aorta from the inside. This new method introduces a strengthening Dacron tube with a stent through an artery in the groin performed whilst you are under anaesthetic. The Dacron is released to lie within the aneurysm near your navel and the intention is to send the blood through this so that it does not touch the walls of the aortic aneurysm. The dotted lines in the figure alongside show where the dacron tube would lie.

Having considered your general condition, we feel on balance that it would be better for us to concentrate on improving your general condition medically rather than selecting the more conventional open operation for abdominal aortic aneurysm. This would require a larger operation to cut through your abdominal wall to get at the swelling deep inside you beneath your navel. We suggest that you receive from us our best medical advice of how to manage your general state, particularly your blood pressure, and if you smoke, your smoking. We have shown that inhalation of tobacco fumes hastens the swelling of an abdominal aortic aneurysm and increases the risk of aneurysm rupture. Thus, if we can persuade our patients not to smoke, the aorta may swell less rapidly. Blood pressure is another very important factor and if our patients have a very carefully controlled blood pressure, we believe that this will be extremely good for them over a period of time. The question we are uncertain about is whether or not in the future we should treat your aorta with this new stent graft system or rely on medical treatment and avoid any operation. We simply do not know whether it is an advantage over and beyond the best medical treatment that is available to you. If the new stent graft method did not work perfectly, this could precipitate the need for an operation to rectify the problem and as you know we are extremely reluctant to recommend the full operation for you. There would be a great risk to your life if we did an open operation.

4. What is the purpose of the study?

Having considered your general condition, it is better for us to concentrate on improving your general condition medically rather than selecting the open conventional operation for abdominal aortic aneurysm. The question we are uncertain about is whether or not in the future we should treat your aorta with this new stent graft system or rely on medical treatment and avoid any operation. We simply do not know whether it is an advantage over and beyond the best medical treatment that is available to you. Therefore, the purpose of this study is to see if the new technique could help you.

5. Why have I been chosen?
Not everyone with an aneurysm is suitable for this new procedure but we have performed some tests and found that your aneurysm could be repaired in this way, and so the matter arises.

6. Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are free to withdraw at any time and without giving a reason. This will not affect the standard of care you receive.

7. What will happen to me if I take part?
As your doctor is uncertain which treatment method would be best for you, the decision as to whether you should or should not be treated with the new stent graft procedure will be made by a method called "randomisation". In medicine, doctors do not always know the best way to treat a patient and therefore we need to make comparisons between the treatments that are available. People who agree to take part in these studies are allocated a treatment which has been selected randomly by a computer. The computer has no information about the individual and the treatment is allocated "by chance". Patients are then given that treatment and the different groups are compared to see which is best.

The vital aspect of this trial is that all patients, whether they have a stent graft replacement or not will get current best medical treatment. The question is whether the stent graft device is of benefit overall. You will need regular checks on your blood pressure, and if you smoke, we hope to convince you to stop as we have shown that an aneurysm grows more slowly in the absence of smoke inhalation. If you receive the stent graft procedure and in any case we need to see you and ask questions about your "quality of life" we suggest to see you three times in the year following trial entry and then once per year for a further 3 years, (6 visits in total). Each visit will not take long. You will have a CT scan performed to check your aorta and you will always be asked some questions about how you feel.

8. What do I have to do?
You do not need to do anything and there should not be any restrictions to your lifestyle.

9. What are the alternatives for treatment?
If you do not wish to take part in this study it is not recommended that you have your aneurysm repaired using the more conventional operation. Your Doctors will provide the best medical treatment they can.

10. What are the possible disadvantages and risks of taking part?
If you are allocated to the new technique, the piece of Dacron tube may not be fixed in place as securely as the more invasive open repair. There is the chance that the stents holding the tube in place may loosen and need correction. If they cannot be corrected you may need to have a "conversion" operation which will replace the Dacron tube with another one using the conventional open repair method. This operation carries an increased risk of complications due to your medical condition.

11. What are the possible benefits of taking part?
It is necessary for us to know if we should be offering this new technique to patients like you in addition to the medical treatment. We need to know so that we can treat all of our patients in the best way. If at first you are not offered a stent device and if the results are better in that group, we shall stop the trial and offer you and future patients the new procedure.

12. What if new information becomes available?
Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens your doctors will tell you about it and we would expect to introduce new therapies, medical or surgical as developments occur.

During this study, we have arranged for an independent data monitoring and ethics committee to audit the data at regular intervals to see that the study is progressing well and there are no problems that put you at unnecessary risk. If it becomes plain that the new procedure is of great benefit and you have not yet received it, we would offer it at once.

13. What happens when the research study stops?
When the study comes to an end, the data will be analysed by medical statisticians. We may then know if there is a difference between the two treatments. If the new stent graft method appears to be doing well, we may need to continue seeing the patients that have been allocated that new treatment so that we can ensure the procedure is durable over a longer period of time. At the moment we do not know if this will happen.

14. What if something goes wrong?
If you are harmed by taking part in this research project there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms may be available to you.

15. Will my taking part in this study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it.

16. What will happen to the results of the research study?
The first analysis will begin in March 2005 and the results will probably be published later that year. If you are interested in receiving a copy of the results we will be happy to provide you with a copy of the published paper. The published report will not identify any individual who participated in the study.

17. Who is organising and funding the research?
The NHS Health Technology Assessment Programme is funding the research.

18. Who has reviewed the study?
Large national studies such as this one need to obtain ethical approval before they can go ahead. The study has been approved by the North West Multi Centre Research Ethics Committee (MREC).

Contact for further information
If you have any queries, you can contact the study co-ordinator for your hospital.
Name _____
Hospital _____
Telephone number __ __ __ __ __ __ __ __ __ __ __ __ __

Centres MUST use headed note paper for participating regional EVAR centre

PATIENT CONSENT FORM

Patient's name : _____

EVAR study number: __ __ __ __ __

EVAR Trial 2 : For patients who have been found to be suitable for the new stent graft aneurysm method but in whom your Doctors are reluctant to recommend the larger conventional open repair operation.

The patient should complete the whole of this sheet by initialing the response boxes:

	Please initial
Have you read the patient information sheet?	☐
Have you had the opportunity to ask questions and discuss the study?	☐
Do you understand that your participation is voluntary and that you are free to withdraw at any time without giving reason, without your medical care or legal rights being affected?	☐
Do you understand that sections of your medical notes may be looked at by responsible individuals from the hospital where you are treated or from regulatory authorities where it is relevant to your taking part in research? Do you give permission for these individuals to have access to your records?	☐
Do you agree to take part in the study?	☐

Signed by patient:_____

Name in block letters: _____

Date of consent: __ __ / __ __ / __ __ __ __