Patient information for EVAR Trial 1

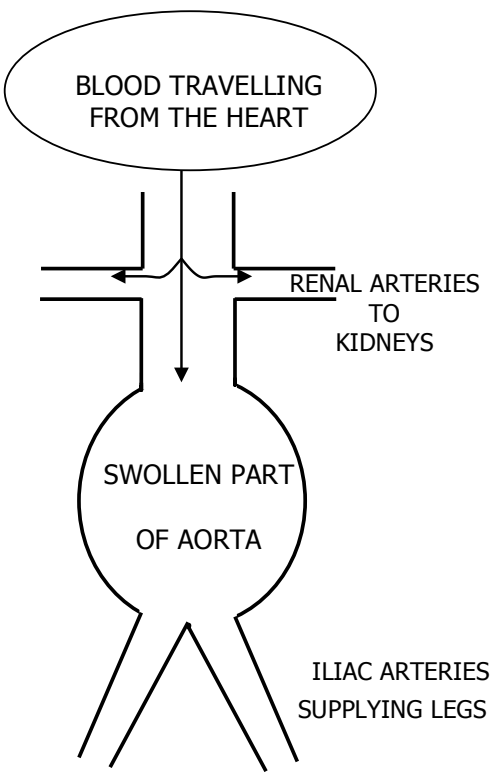
For patients with abdominal aortic aneurysms suitable for either conventional open repair or new stent graft repair method.

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 1. The trial is for patients with abdominal aortic aneurysms suitable for either conventional open repair or new stent graft repair method.

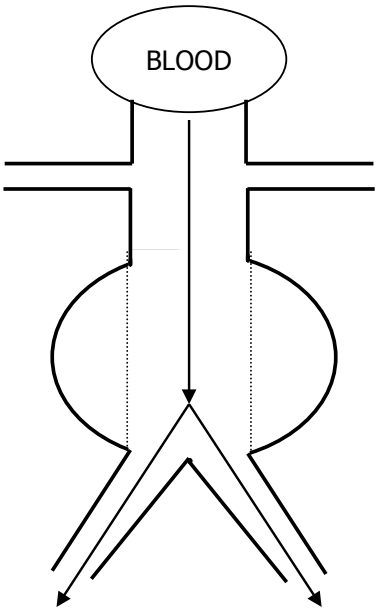
2. What is an Abdominal Aortic Aneurysm?



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 might rupture. If it did so, it could occur suddenly and might possibly lead to an emergency operation.

3. How are Abdominal Aortic Aneurysms treated?



We believe that the best method to treat your aneurysm is to perform an operation to take the strain off the weakened part of your aorta. A man made fibre called Dacron is used to make a tube which is attached within the swelling so that blood will flow through the Dacron instead of stretching your aorta further. This is done under a general anaesthetic and the dotted lines in the figure alongside show where the Dacron would be placed.

4. What is the purpose of the study?
There are now two different ways of fixing the Dacron tube into your aorta. The time honoured method is to cut through your abdominal wall, clamp and open your aorta, and sew the tube in place. This has the advantage of having been tried and trusted and is known to be reasonably durable. The disadvantage is that it has the rather large incision near your navel. A newer method is proposed which fixes the Dacron tube into place by a stent or clip which attaches the Dacron tube from within the aorta. The tube enters the aorta through an incision in the groin and is moved upwards through the artery in your leg until it is at the swollen part of your aorta. With this newer method you have a smaller incision than the traditional method but we are not certain about how durable the new method is. At this stage we simply do not know if one treatment is better than the other.

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 by either of the surgical techniques.

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 receive open repair or 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.

In this study, you will receive either the traditional open repair or the new stent graft method and you will have your aneurysm repaired in the near future. After you have had your operation we would like to keep seeing you for some time to check that the method has worked properly and also to ask you some questions about your “quality of life” as a result of the treatment you have received. We will need to see you three times in the year following your operation and then once per year for a further 3 years, (6 visits in total). Each visit will not take long. You will have a scan done to check that the operation has taken the strain off your aorta and you will also be asked some questions about your “quality of life”.

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

9. What are the alternatives for treatment?
If you do not wish to take part in this study it is still recommended that you have an operation to repair your aneurysm. This will be performed using the open repair technique. If you do not have an operation you have a risk of aneurysm rupture and death but there is also risk of death from operation for either of these methods. Both are in use at present and we do not know which is better.

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 traditional open repair method.

11. What are the possible benefits of taking part?
The traditional open repair method requires quite a large incision down your abdomen. The operation can also put extra stress on your heart and lungs during the operation and this might cause some problems afterwards. If you are offered the new technique, your heart and lungs will be effected very little during the operation and you may be less likely to have problems following this procedure. You will also have a much smaller incision scar and may recover more quickly after the new stent technique.

We hope that either of the treatments will help you. However, this cannot be guaranteed. The information we will get from this study may help us to treat future patients with the same condition better.

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 surgeon will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw your surgeon will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

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 risk. If at any time one method is seen to be superior to the other, then we would immediately stop the one and switch all our patients to the better method.

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 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: __ __ __ __ __

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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: __ __ / __ __ / __ __ __ __