Making a decision about joining the WARRIORS trial

WARRIORS trial

What is this document?

- **This document is called a decision aid. It is designed to help you decide between treatment options**.
- It is for women that have small abdominal aortic aneurysms and are otherwise suitable to be in the WARRIORS trial.
- After reading the patient information sheet, you may use the information in this decision aid to help make your choice and to use it to talk to your surgical team. It can also be used to talk to the other members of the multidisciplinary team (in other words the nurses, anaesthetists, and other health professionals involved in your care).
- The decision aid is a guide only because each woman will be different and your situations and feelings are unique to you.

Go to page 3 for information about your options

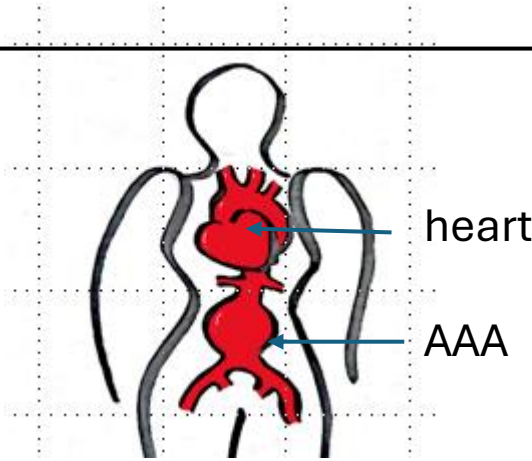
Go to page 9 for help with making your decision

1 About your small abdominal aortic aneurym

An abdominal aortic aneurysm (AAA) is a swelling of the main blood vessel of the body (the aorta) that supplies blood from the heart to the tummy and the legs.

You can see what this looks like on the diagram here

An AAA between 4cm and 5 ½ cm wide is classified as a “small” AAA.



When the AAA is small, the swelling does not normally cause any symptoms or problems, but it will steadily grow larger over time. As the swelling continues to grow, the wall of the aorta becomes weaker and there are no treatments known which stop the steady growth of the AAA once it has formed.

Once the AAA becomes too large, it may burst. If this happens, it is very dangerous, causing bleeding inside your tummy, and death in 8 out of 10 cases. So it is important for people with this condition to have the best possible care to prevent this from happening.

Does having an AAA affect what I can do?

You should be able to live a normal life with an AAA, and it is alright to continue to exercise.

As the AAA is small, you may still drive. If you have a car or motorcycle licence you only need to tell the DVLA if your AAA is 6 cm or more. You are allowed to drive until your AAA is 6.5 cm or more.

There is no increased risk if you travel by plane if you have an AAA. It is no more likely to burst because of cabin pressure at a high altitude than on the ground. However, you should declare your AAA when applying for insurance. You may be charged a higher premium or have the AAA excluded from your insurance cover.

2 Where can I go for more information about aneurysms?

- **Circulation foundation:**
- https://www.circulationfoundation.org.uk/help-advice/abdominal-aortic- aneurysm/open-aaa-repair operation
- **British Heart Foundation:**
- https://www.bhf.org.uk/informationsupport/conditions/abdominal-aortic-aneurysm
- **NHS:**
- https://www.nhs.uk/conditions/abdominal-aortic-aneurysm/

3 What are my options?

- This decision aid specifically helps you to decide whether to enrol in the WARRIORS trial.
- You have two choices:
- Regular monitoring (standard care)
- Consenting to enrol in the trial

- ***Option 1: Regular monitoring***

- You will continue to be looked after by the medical team at your local hospital who will check whether your AAA is growing bigger. Most patients are offered an ultrasound (jelly scan) for this on a regular basis.
- You will continue on any medication you take to make it less likely that the AAA bursts or that you have a heart attack or stroke. Giving up smoking and managing your blood pressure will make it less likely that your AA will grow quickly or burst.
- It is important that you understand that at this size the risk of rupture is low, you may still drive and travel safely.
- If the aneurysm reaches 5 ½ cm in size you will most likely be offered surgical repair.
- The surgery to repair the AAA may either be by a big cut in the tummy (open surgery) or by a small cut in the groin (keyhole surgery).
- The keyhole operation is called an EVAR (endovascular aortic repair). It carries a lower risk than open repair. More information on this is provided below. Although your AAA is suitable for keyhole surgery now, it may not be when it grows to 5 ½ cm. In this case you may need open surgery. We cannot predict whether you will need EVAR or open repair at this stage.
- Your medical care will not be affected if you choose not to be in the trial.

- ***Option 2: Consenting to enrol in the trial***

We are conducting a large research trial around the world asking the question whether we should repair an AAA, using keyhole repair (EVAR) at a smaller size in women.

Repairing AAAs at a smaller size in women may have advantages. If the repair is earlier, more women are suitable for a keyhole approach, may be younger and fitter. The repair is easier when AAAs are small and so there may be less risk of complications.

If you are enrolled in the trial, you will be allocated, at random, to be in one of two groups. You will not have a choice which group you are in. The groups are:

- Early Endovascular Aneurysm Repair (EVAR)
- Surveillance (standard care)

In both groups you will have a review of any medications you take, to make it less likely that the AAA bursts or that you have a heart attack or stroke. You can make it less likely that your AAA will grow quickly or burst by stopping smoking (if you smoke, support to quit will be offered).

The table below shows you what you can expect if you are allocated to one or the other group

The tables on the next 3 pages show what you can expect if you are allocated to one or the other group

Endovascular Aneurysm Repair (EVAR)	Surveillance
PROCEDURES Within the next eight weeks you will be offered a repair of the aneurysm with a keyhole technique (EVAR). The surgeon uses small cuts at the top of the leg to insert special equipment into your arteries and reline the AAA with a new tube from the inside. This should stop the AAA from growing. The procedure is generally safe, and patients will normally only need to stay in hospital for a day or so to recover.	PROCEDURES No procedure at the start of the trial is offered If your AAA grows to 5½ cm, shows signs of bursting or bursts, you will have surgery to repair it. Otherwise, your treatment will be ultrasound (jelly scan) monitoring Surgery is likely to be needed in about half the women in this group within 5 years. The shape of your AAA may change as it grows and when surgery is needed your AAA may no longer be suitable for keyhole surgery. If this happens, surgery to repair the AAA may be by a big cut in the tummy (open surgery) rather than by a small cut in the top of the leg (keyhole surgery).
TREATMENT DURING THE FIVE YEARS IN THE TRIAL Apart from the above procedure, your treatment is exactly the same in both groups AND exactly the same as would occur if you were not part of the trial. You will be followed up for 5 years in the trial. You will attend clinic visits with your normal clinical team You will be offered the best available medicines to reduce your risks of heart disease and other diseases of the blood vessels. At the beginning and again after 1, 3 and 5 years, you will be asked some questions about how easy and enjoyable your life is and how you feel about having an AAA.	TREATMENT DURING THE FIVE YEARS IN THE TRIAL Apart from the above procedure, your treatment is exactly the same in both groupsAND exactly the same as would occur if you were not part of the trial. You will be followed up for 5 years in the trial. You will attend clinic visits with your normal clinical team You will be offered the best available medicines to reduce your risks of heart disease and other diseases of the blood vessels. At the beginning and again after 1, 3 and 5 years, you will be asked some questions about how easy and enjoyable your life is and how you feel about having an AAA.

Endovascular Aneurysm Repair (EVAR)	Surveillance
MONITORING If you are randomly selected for the EVAR group and undergo the procedure, then the stent will need monitoring. After the procedure, you will then return for a CT scan and a clinic visit to check on the AAA repair at about 6 weeks and again after 1 year. After that you will be asked to come back once every year, for another scan, which normally will be an ultrasound scan. These scans may pick up a problem with the stent and means that further investigation and treatment is necessary.	MONITORING If you are randomly selected for the surveillance group, then your AAA will be monitored to check the size of the AAA and make sure that it is not causing any problems. This is usually done with a "jelly" scan called an ultrasound, which is painless and risk-free and takes only a few minutes. The scans will be done every 6-12 months but may be more often as the AAA grows bigger. If an AAA reaches 5½ cm (2.2 inches) wide or grows rapidly your surgeon will discuss with the you and your family whether now is the right time for you to have an AAA repair.
WHAT ARE THE POSSIBLE BENEFITS TO BEING IN THIS GROUP? You will be regularly and closely monitored. In the trial you should receive excellent care for your AAA. If you are selected in this group, you will Have the operation to repair your AAA soon. All operations carry some risks, so these risks will come soon too. However, these risks are normally less for smaller AAAs and at younger ages and most patients leave hospital the next day after repair. Once your AAA is repaired, your aorta is very unlikely to burst. As the AAA is repaired at a small size with a keyhole technique there is a low risk of death. The actual risk we calculate to be between 1 and 2 per 100 women. Equally there is a very low risk of complications from repair.	WHAT ARE THE POSSIBLE BENEFITS TO BEING IN THIS GROUP? You will be regularly and closely monitored. In the trial you should receive excellent care for your AAA. In this group there are no immediate risks, as no one will receive an early operation. There is a chance your aneurysm may never grow large enough to need to be repaired.

Endovascular Aneurysm Repair (EVAR)	Surveillance
WHAT ARE THE DISADVANTAGES TO BEING IN THIS GROUP? The risk of undergoing repair will happen soon after you consent for the trial. You will have a little more exposure to radiation (from placing the EVAR stent graft and 2 monitoring CT scans) at a younger age. After EVAR, your stent will need monitoring. There is a risk of a leak occurring around the stent which needs repair. About 1 in 10 women will need another small procedure to strengthen the repair.	WHAT ARE THE DISADVANTAGES TO BEING IN THIS GROUP? As the AAA has not been repaired your AAA is at greater risk of bursting as it grows. As your AAA grows, its shape changes so that later keyhole repair may not be possible for you and a bigger open surgical procedure may be necessary. About half of women will need a repair within 5 years. If there is a repair later in the course of the disease, there will be a higher risk of death. The actual risk we calculate to be 4 per 100 women. Equally there is a higher risk of complications from repair compared to the group where the AAA is repaired at a smaller size.
COSTS After the initial assessment and EVAR procedure, we will not expect you to come to hospital for any visit that would not be part of your standard care. Any extra questionnaires should be posted to you and will take a little time to fill out only. You will not be expected to pay postage fees to return the questionnaires.	COSTS After the initial assessment, we will not expect you to come to hospital for any visit that would not be part of your standard care. Any extra questionnaires should be posted to you and will take a little time to fill out only. You will not be expected to pay postage fees to return the questionnaires.

4 Things to think about when considering whether to be part of the trial

For each of the following considerations, put an X where your thoughts lie (more x on the right-hand side favour joining ther trial)

Being involved in a trial:

1 What do I think about the importance of the trial?_

Scale

- 1……..5……..10 (the trial is very important)

2 Am I happy going into a trial that may not improve things for me, but might help women across the world?

Scale

- 1……..5……..10 (very important to help others)

- 3 Am I prepared to undertake the extra monitoring needed for the trial ?

Scale

- 1……..5……..10 (not a concern)

4 Will I feel safer being in a medical trial ?

Scale

1……..5……..10 (more secure)

Treatment options:

5 Am I happy that my treatment will be randomly selected to a treatment?

Scale

1……..5……..10 (not a concern)

6 Thinking about the risks of surgery if allocated to the keyhole repair (EVAR) group in the trial

Scale

1(I am very worried)……..5……..10 (I am not so worried the risk seems low)

Overall:

My thoughts, concerns or questions to discuss with the research team and clinical team.

……

Where can I go for more information about being part of a clinical trial?

https://bepartofresearch.nihr.ac.uk

https://www.bhf.org.uk/what-we-do/our-research/impact-of-clinical-trials

5 Making the decision

- Think about whether joining the trial is right for you at the moment.
- You do not have to make this decision straight away. You can take some time and ask your surgical team for more information. Do not be afraid to ask your surgical team about the results in their centre, or other questions that come to mind. Surgical teams really want people to make the decision that feels right for them.
- You might also want to discuss things with family and friends.It might be helpful to ask a friend or family member to come with you when you talk to your surgical team. But remember that although you decision may have an impact in them, it is you who will be directly affected, whatever you decide to do.
- Lastly, remember it is OK to change your mind. If you choose to be part of the trial you can change your mind at any time and will continue your surveillance and treatment with your clinical team. Your care will not be affected.

6 Things to check & next steps

Things to check

- I have enough support and advice to make a choice Yes No
- I know enough about the potential benefits and harms of each option Yes No
- I am clear about which potential benefits and harms matter most to me. Yes. No
- I feel sure about the best choice for me Yes. No
- If you said 'no' to any of these, tell your research contact or your surgical team and ask them for help]

Next steps

- **My thoughts at the moment**
- I am not sure whether to join the trial because…….
- I want to join the trial because…….

Things I want to talk about with my surgical team

- These can be concerns or questions you have, or what you hope to get from what you decide to do
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