

IMPERIAL



Making a decision about joining the

EARNEST Trial

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What is this.

This document is called a decision aid. It is designed to help you decide whether to go into the EARNEST trial.

It is for patients with uncomplicated type B aortic dissection who are suitable to be entered into the EARNEST 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 surgeons, nurses, anaesthetists, cardiologists and other health professionals involved in your care).

The decision aid is a guide only because your situation and feelings will be unique to you and will be different from other patients.

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About your uTBAD.

An uncomplicated type B aortic dissection is a serious condition where a tear occurs in the inner lining of the wall of the aorta, the large blood vessel that carries blood from your heart to the rest of your body. The tear occurs in the part of the aorta that supplies all the lower body, called the “descending” thoracic aorta.

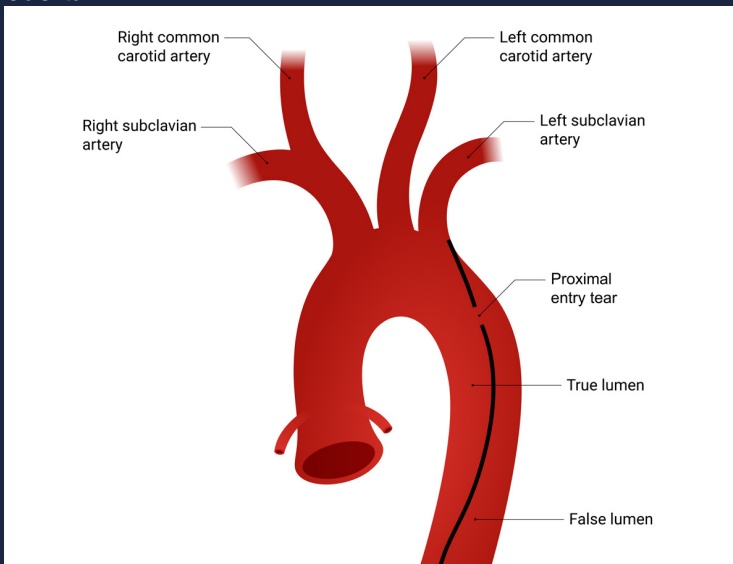


Diagram of an aortic dissection.

When the tear happens, blood is pushed between the layers of the wall of the aorta, which can cause the layers to separate. This is called a dissection. The word “uncomplicated” means that there are no immediate life-threatening complications, like the tear causing major damage to other organs or sudden expansion of the aorta which can lead to internal bleeding, but it still needs medical treatment to make sure the condition is stabilised. Doctors usually treat it with medication to help manage the blood pressure and keep the tear from getting bigger.

Doctors usually treat a dissection with medication to help control blood pressure and reduce the risk of the tear getting bigger. While it is often safe to monitor the dissection, it can, over time (months to years), progress and lead to the development of an aneurysm, which is a balloon-like swelling or bulge in a blood vessel. If an aneurysm develops, it usually requires repair with a complicated operation, as without treatment it may continue to enlarge, rupture, and become life-threatening.



02

Where can I go for more information about aortic dissection?

[The Aortic Dissection Charitable Trust](#)

[Aortic Dissection Awareness UK & Ireland](#)

[British Heart Foundation](#)

[Circulation Foundation](#)

What are my options?



This decision aid specifically helps you to decide whether to enrol in the EARNEST trial.

You have two choices:

1. **Regular monitoring (standard care),** [click here to see more info](#)
2. **Consenting to enrol in the trial,** [click here to see more info](#)



Regular monitoring.

You will continue to be cared for by the doctors and nurses at your local hospital. You can go home when your blood pressure is stable, and the medical team is convinced that the condition of the aorta is stable.

Your local medical team will keep an eye on your condition after uTBAD (the tear in your aorta). They will check your blood pressure at the hospital, and they'll adjust your medicine if needed.

You will also need regular CT scans to see if there are any changes in the aorta, like it getting bigger and forming an aneurysm. About one in three patients have this happen.

Stopping smoking and keeping your blood pressure under control can help slow down the growth of any aneurysm in the aorta.

If the aneurysm stays small, the risk of it bursting is low, and you can still drive and travel safely. If the aneurysm gets larger (usually when it reaches 5.5–6 cm), doctors may suggest surgery to fix it. The surgery can be complex.

There are two types of surgery:

1. Open surgery: Doctors make cuts in your tummy and chest to replace the weak part of the aorta with a fabric graft.

2. Keyhole surgery: Doctors make a small cut in your groin and use an X-ray to guide a fabric tube with a metal frame (called a stent graft) into your aorta. The stent graft realigns the aorta, supporting it and keeping blood flowing properly. In many cases, the aneurysm then shrinks over time.

If you don't want to be part of a trial, it won't change how your medical care is handled.

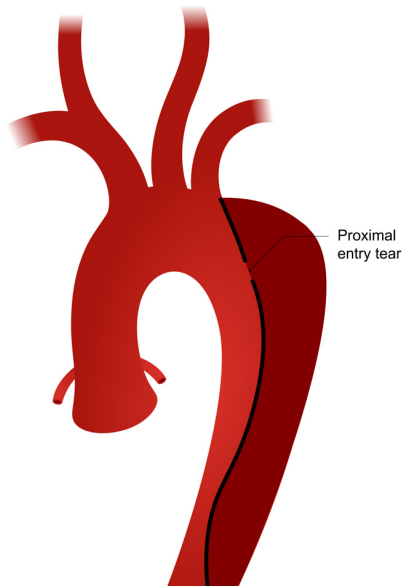


Diagram of an aortic aneurysm.



Consenting to enrol in the trial.

We are doing a large research study in the UK to find out if repairing a tear in the aorta early, between 5 days and 3 months after it happens, can be helpful. This repair is called Thoracic Endovascular Aortic Repair (TEVAR).

The TEVAR procedure usually requires general anaesthesia (so you're asleep during the surgery). Doctors make a small cut in your groin to access a blood vessel, then use an X-ray to guide a stent graft (a fabric tube with a metal frame) into the aorta. Once it's in the right place, the stent is released, and it relines the aorta. The tear in the inner lining of the aorta is closed and so the blood is redirected through the stent graft and not permitted to go between the layers of the aorta.

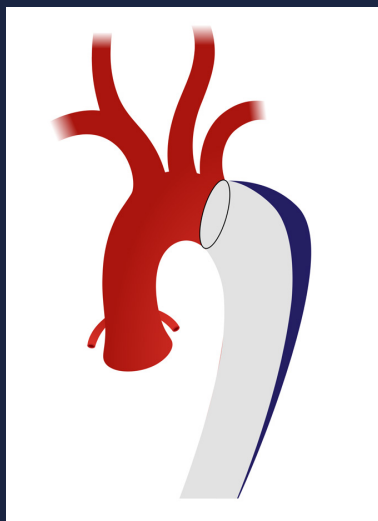


Diagram of a TEVAR inserted into the aorta.

Repairing the aorta early may have some benefits:

It could help the aorta heal and stop the aorta from getting bigger over time. This means there's less chance of the needing an operation to prevent aortic rupture.

An early operation may be less complicated and safer than doing surgery later when the aorta might be bigger and more damaged.

If you join the study, you'll be randomly put into one of two groups. You won't be able to choose which group you're in. The groups are:

1. **TEVAR group:** You'll have the surgery to repair the aorta.
2. **Surveillance group:** You'll receive standard care and regular check-ups without surgery, unless medically indicated.

In both groups, you'll get regular checks for your blood pressure and medications to help prevent complications from the uTBAD. If you smoke, quitting can help reduce the risk, and you'll be offered support to stop. You'll also have regular CT scans to keep track of what's happening with your aorta.

This study will help doctors understand the best way to treat uTBAD and prevent patients from developing long term complications.



What to expect.

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

TEVAR + BMT + SURV

Procedures -

Within 3 months after your uTBAD, you will have a TEVAR operation to repair the tear in your aorta. This is usually done while you're asleep under general anesthesia.

During the surgery, doctors make a small cut in your groin to insert a stent-a fabric tube with a metal frame-into your aorta. They use an X-ray to guide the stent to the right place, and once it's in position, the stent helps seal the tear in the aorta.

This procedure is well-known and safe, and it will leave a small scar on your groin.

After the operation, you'll be looked after in a special area for close monitoring for a short time. Most people stay in the hospital for about 3 to 5 days in total. After you leave, the doctors will continue to check your aorta using CT scans to make sure everything is healing properly.

Treatment during the five years in the trial -

Apart from the TEVAR surgery, your treatment will be the same as the standard care group, and it should feel like you are receiving the usual treatment, whether or not you're part of the trial.

You will be followed up for 5 years as part of the study. You will go to regular check-ups with your usual medical team.

Your blood pressure will be closely watched, and you'll be given the best available medicines to lower your risks of heart disease and other problems with your blood vessels.

At the start of the study, and then again after 6 weeks, 6 months, 12 months, and every year after that for up to 5 years, you will be asked some questions about how you're feeling and how easy or enjoyable life is for you. You'll also be asked about any medical help you've needed since your last visit to the hospital.

BMT + SURV

Procedures -

At trial entry, no procedures will be conducted; participants will receive interventions as allocated.

The aorta **will** be monitored on CT scans, and if the aorta grows and becomes an aneurysm that is at significant **risk** of bursting then you may be recommended an operation at a later stage.

Treatment during the five years in the trial -

You will not have TEVAR surgery, but otherwise your treatment will be exactly the same as the other group in the study and will be just like the treatment you would receive if you weren't part of the trial.

You will be followed up for 5 years in the trial, attending regular clinic visits with your usual medical team.

Your blood pressure will be carefully monitored, and you **will** be given the best available medicines to help lower your risk of heart disease and other blood vessel problems.

At the start of the trial, and then again after 6 weeks, 6 months, 12 months, and every year after that up to 5 years, you will be asked questions about how you're feeling, how easy and enjoyable life is for you, and how you feel about having an uTBAD. You will also be asked if you've needed any medical support since your last visit to the hospital at each follow-up appointment.



What to expect.

TEVAR + BMT + SURV

Monitoring -

If you are randomly selected for the TEVAR group and have the procedure, the stent will need regular check-ups.

After the surgery, you will have a CT scan within 6 weeks and a clinic visit around 6 weeks to check that the repair is healing properly.

At 6 months, you will have another clinic appointment to see how you're feeling after the operation and to monitor your blood pressure.

After that, you will have a check-up once a year, which will usually include a CT scan. These scans help doctors spot any problems with the stent early. If an issue is found, you may need further tests or treatment.

What are the possible benefits to being in this group? -

You will be closely monitored and receive excellent care for your aortic dissection as part of the trial.

If you are selected for this group, you will have the TEVAR operation soon to repair the tear in your aorta. Like all surgeries, this procedure carries some risks, which will be explained to you.

Since the uTBAD is repaired early, before an aneurysm forms, using a keyhole technique, the risk of death is low. There is also a very low risk of complications from the repair.

Once your uTBAD is repaired, your aorta is likely to heal well, reducing the chance of it expanding or forming an aneurysm in the future.

BMT + SURV

Monitoring -

If you are randomly selected for the surveillance group, your uTBAD will be closely monitored to check the size of the tear and ensure it is not causing any problems.

This is usually done with CT scans, which will be scheduled 6 weeks after you leave the hospital, at 12 months, and then once a year.

If your aorta starts to expand and reaches 5.5-6cm, a surgeon will talk with you and your family about whether it is the right time to consider repairing it with an operation.

What are the possible benefits to being in this group? -

You will be closely monitored and receive excellent care for your aortic dissection as part of the trial.

In this group, there are no immediate risks because you will not have an early operation.

There is a good chance that your aorta may never grow large enough to need surgery.



What to expect.

TEVAR + BMT + SURV

What are the disadvantages of being in this group? -

The risks of having the repair will happen soon after you agree to take part in the trial.

You may be exposed to a small amount of extra radiation during the procedure when the TEVAR stent is placed.

After TEVAR, your stent will need regular monitoring. There is a risk that a leak could develop around the stent, which might require another operation to fix.

Costs -

After the initial assessment and TEVAR procedure, we will not expect you to come to hospital for any visit that would not be part of your standard care.

BMT + SURV

What are the disadvantages of being in this group? -

Since your uTBAD has not been repaired, your aorta is at a higher risk of forming an aneurysm. If this happens, there is a risk that it could burst as it grows.

If surgery is needed later, it is often more complex. There are two possible types of repair:

Open surgery: A cut is made in the tummy and chest to replace the weakened part of the aorta with a fabric graft.

Keyhole surgery: A small cut is made in the groin, and a stent graft is placed inside the aorta using X-ray guidance.

As the aorta grows, its shape changes, which means that keyhole surgery may no longer be possible, and a larger open surgery may be needed.

If a keyhole approach is still an option, doctors will use a stent, which is a fabric tube with a metal frame. The stent seals off the aneurysm, allowing blood to flow safely through the aorta. This often requires a custom-made stent with branches to maintain blood supply to the internal organs.

If surgery is done later in the disease, no matter which method is used, the risk of death and complications is higher compared to repairing the tear earlier.

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.



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Things I now understand...

I don't have to go into trial.

If I enrol into the trial, I will be randomly allocated to either TEVAR plus standard care or standard care alone. In both groups, I will be closely monitored and my blood pressure will be managed carefully.

If I am randomly allocated to standard care, I may never need an operation. However, if my aorta expands or my condition changes, I may need an operation at a later date.

If I am randomly allocated to TEVAR, I will have a procedure earlier in my care. As with any procedure, TEVAR has potential risks as well as possible benefits.

The purpose of the trial is to find out which approach leads to better outcomes overall.



Being involved in a trial.

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

For each of the following considerations, click on a box where your thoughts lie (1 being less favourable and 10 being the most favourable for joining the trial)

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

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

1 2 3 4 5 6 7 8 9 10 (the trial is very important)

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

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

1 2 3 4 5 6 7 8 9 10 (very important to help others)



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

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

1 2 3 4 5 6 7 8 9 10 (not a concern)

4. Will I feel safer being in a medical trial?

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

1 2 3 4 5 6 7 8 9 10 (more secure)

Treatment Options.

For each of the following considerations, click on a box where your thoughts lie (1 being less favourable and 10 being the most favourable for joining the trial)

Number 7 is an open text box, please click in the box to type any thoughts, concerns or questions that you can discuss with the research and clinical teams.

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

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

1 2 3 4 5 6 7 8 9 10 (not a concern)

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

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

1 2 3 4 5 6 7 8 9 10 (not worried, the risk seems low)

7. Overall, my thoughts, concerns or questions to discuss with the research team and clinical team....





More information.

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

[Be Part Of Research](#)

[British Heart Foundation](#)

Making the decision.

Take some time to think about whether joining the trial is the right choice for you.

You don't have to decide straight away. You can take some time to consider your options and ask your surgical team for more information. However, you can only join the trial within 3 months after your dissection. Feel free to ask your surgical team about the results at their hospital or any other questions you have—they want to help you make the decision that feels right for you.

Talking to family and friends may help. You might find it useful to bring someone with you when you speak to your surgical team. While your decision may affect those close to you, you are the one directly impacted, so it's important that you make the choice that feels best for you.

It's OK to change your mind. If you decide to join the trial but later change your mind, that's completely fine. You will still receive the same care and monitoring from your clinical team, and your treatment will not be affected.

Things to check and next steps.

1. I have enough support and advice to make a choice?

☐

Yes

☐

No

2. I know enough about the potential benefits and harms of each option.

☐

Yes

☐

No

3. I am clear about which potential benefits and harms matter most to me.

☐

Yes

☐

No

4. 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.

5. My thoughts at the moment.....

6. I am not sure whether to join the trial because.....

7. I want to join the trial because.....

8. 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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