Insert hospital letterhead and local team contact details

BHF PROTECT-TAVI

Participant Information Sheet

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Study title: British Heart Foundation Randomised Clinical Trial of Cerebral Embolic PROTECTion in Transcatheter Aortic Valve Implantation (BHF PROTECT-TAVI)

We would like to invite you to take part in a research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please take time to read this information carefully before you decide whether or not to participate in this study. One of our team will go through the information sheet with you and answer any questions you have. Please talk to others about the study if you wish. Ask us if there is anything that is not clear.

Information about the research

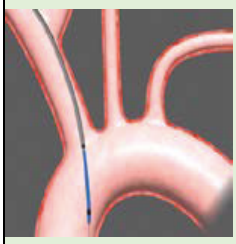
Transcatheter Aortic Valve Implementation (TAVI) is a standard treatment for Aortic Stenosis (AS), a condition where blood flow out of the heart is restricted by narrowing of the aortic valve. In a TAVI procedure, the aortic valve is replaced by placing a new valve delivered to the heart through a tube (catheter) placed in an artery. One risk associated with TAVI is stroke. During the TAVI procedure, debris (made up of parts of the diseased aortic valve and the surrounding tissue) can be released into the bloodstream. Most strokes occurring at the time of TAVI are due to this debris blocking part of the blood supply in the brain. Devices have been developed that capture some of the debris released and stop this reaching the brain, these are called Cerebral Embolic Protection (CEP) devices.

The purpose of this study is to assess whether using a Cerebral Embolic Protection (CEP) device during Transcatheter Aortic Valve Replacement (TAVI) can reduce the chance of a patient having a stroke. The study will also determine whether it improves the quality of life for patients and how the use of CEP impacts the NHS in terms of cost and service use.

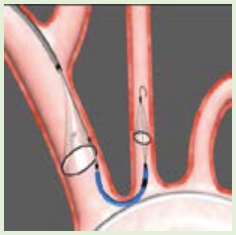
What is Cerebral Embolic Protection?

The Sentinel Cerebral Protection System is a device that may offer protection from the risk of stroke during TAVI. It works by capturing debris released during TAVI and removing it before it can reach the brain. Some studies have shown that the device is safe, that it removes visible debris from blood vessels that supply the brain and that it may reduce TAVI-related strokes. The device is now used across the world in some TAVI procedures, but we do not know that it definitely reduces stroke.

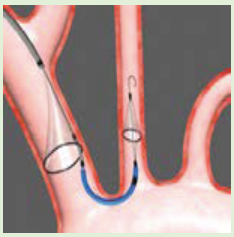
How do we use the device?



Step 1: The device is delivered at the beginning of the TAVI procedure through a small tube (catheter) inserted into a wrist or arm artery. This is a catheter line, and it involves standard risks associated with inserting a tube such as infection and bleeding.



Step 2: Using a catheter (tube), two tiny filters are placed in the two main arteries feeding the brain. This takes approximately 5-10 minutes.



Step 3: Throughout the TAVI procedure, the filters collect debris and prevent it from traveling to the brain. At the completion of the TAVI procedure, the filters and collected debris are recaptured into the catheter and removed from the body.

Why have I been invited to join?

You have been invited to join this study because you are scheduled to have a TAVI.
In total this study aims to recruit 7730 participants.

What will happen to me if I take part?

Those who agree to take part (this means given written consent) will be assigned to either receive their **TAVI procedure as normal (CONTROL GROUP)**, or to receive **TAVI with Cerebral Embolic Protection (INTERVENTION GROUP)**. This assignment is done using a computer program at the time of your TAVI procedure. Randomisation ensures that the two groups are similar. You have a 1 in 2 chance of being allocated to either the control group or the intervention group. This ensures that we have two groups which we can compare scientifically and answer the question of whether these devices reduce stroke. This allows us

to better understand how to guide the treatment of patients in the future. Both groups are equally important in this study.

Taking part does not mean that you cannot participate in other research studies. If you are already taking part in a research study, you can most likely still take part in this study. Please discuss this with your local research team.

Control Group: TAVI procedure as normal
You will receive the TAVI procedure you have been scheduled to receive. This is the standard treatment for patients with your condition.

Intervention group: TAVI with Cerebral Embolic Protection
Alongside your TAVI procedure you will receive the CEP device. This will be delivered through a catheter in your arm, and will be removed before the end of your TAVI procedure. All other parts of your care will remain unchanged. It is possible that during your TAVI procedure the cardiologist who is performing it may decide that the CEP device is not suitable for you. If this happens, the device will not be used. We will discuss this with you after your TAVI procedure.

Follow-up
If you agree to join this study, we will follow how your health progresses while you are in hospital after your TAVI procedure, between 6-8 weeks and at 12 months to track how you are doing.

We will record some of the data that is collected as part of your normal care around your TAVI procedure during your stay in hospital. This will include details about your medical history, current medication, TAVI procedure and discharge as well as how long you spent in hospital, what treatments you required, and how well you recovered.

We will use your NHS number to collect some information about your health, medical tests and hospital visits.

If you agree to take part, there will be some questionnaires to assess your health and quality of life. These will be done either in person or over the phone and are detailed below. We will use hospital records to confirm your health status prior to contacting you.

<u>Visit 1: Between 6-8 weeks after your TAVI</u>
We will contact you via phone or in person if you have a hospital appointment arranged in order to complete cognitive assessment questionnaires. This will take no more than 15 minutes.

Visit 2: 12 months after your TAVI

We will contact you via phone or in person if you have a hospital appointment arranged in order to complete the cognitive assessment questionnaires. We will also use a questionnaire to assess your quality of life. This will take about 30 minutes.

Will any other tests be done?

Yes. During your stay in hospital you will receive a short questionnaire called the Questionnaire to Verify Stroke Free Status. This will be administered daily up to 72 hours after your TAVI procedure or until to you are discharged from hospital, whichever happens first. This questionnaire will be administered in person and takes no more than 15 minutes to complete.

Do I have to take part?

You do not have to agree to take part. If, as is your right, you choose not to participate in any aspect of the study, your treatment or care that you receive will not be affected in any way.

If you decide to take part in this study you will be asked to sign a consent form. You will be given this information sheet to keep together with a copy of the signed consent form.

It is important to know that you are free to withdraw at any time. You do not need to give a reason if you choose to withdraw. If you decide to withdraw, your treatment or care you receive will not be affected. We will continue to collect information remotely about your overall health unless you write to us specifically to request that we do not.

Payment

You will not be paid for participating in the study.

What are the possible disadvantages and risks of taking part?

We have no evidence that there are significant risks associated with using the CEP device. There are small risks associated with putting a device within an artery. These risks are less than 1% and include bleeding, infection or damage to the artery. The additional risks from the device are small.

The risks of a TAVI procedure itself include a 2-3% risk of stroke or death and a 10% risk of bleeding. You will be attended to and cared for by the standard care and clinical team throughout the procedure and your recovery.

If you take part in this study you will have a heart valve replacement procedure as part of your routine care. For some participants the procedure will be extended by about 10 minutes to place a cerebral embolic protection device. This time and procedure are extra to what you would have if you did not take part.

There is a small chance that patients in the TAVI with CEP arm will have to receive an small additional dose of X-ray contrast associated with the use of the CEP device. This could cause an injury to the kidney, however there are no reported cases of this happening to date.

The operation you are having uses ionising radiation to form images of your body. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. Dose levels are monitored carefully during your intervention.

We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. Having this procedure might increase the chances of this happening to you from 50% to 50.13% (this means that 13 in 1000 patients) might develop cancer. If you are in the group receiving CEP, the time for this radiation would be extended by 10 minutes.

What should I consider?

In deciding whether you would be willing to participate in this research, you should consider the potential risks discussed in the previous section as well the commitment to be contacted by the researchers to complete questionnaires twice in the 12 months following your TAVI. If you have any concerns, please make sure you discuss them fully with your family and friends, as well as the doctors and nurses responsible for your care.

What if we find something unexpected?

Should any findings of clinical significance be discovered through your participation in this research, they will first be referred to the doctor in charge of your care for clinical verification.

How have patients and the public been involved in this study?

Patients and the public have been involved throughout the design of this research and play in an active role in overseeing its conduct. Participant materials have been reviewed by patients. Patient opinions were key to selecting the key outcomes, and follow-up frequency was discussed with patients.

What are the possible benefits of taking part?

There is some evidence that CEP may reduce the risk of stroke associated with TAVI, but we do not know this for certain and you would not routinely be offered CEP as part of routine TAVI in the UK currently. By participating in the trial you may receive the CEP treatment if you are allocated to that group. Your participation in this study will help us to answer this important question and potentially improve the care received by future patients.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you and your medical records, NHS Digital and other central NHS registries in order to undertake this study and will use the minimum personally-identifiable information possible.

The [INSERT LOCAL TRUST NAME] will use your name, NHS number, home address, and contact details to contact you about the research study, and to oversee the quality of the study. They will keep identifiable information about you from this study keep identifiable information about you for as little time as possible (no more than 3 months) after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely for 15 years after the end of the study.

Your NHS number will be transferred securely to the London School of Hygiene and Tropical Medicine Clinical Trials Unit, which is running this study. It will be used to collect routine data about your NHS use in order to understand how the use of CEP impacts the NHS.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at: https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by emailing: bhfprotect-tavi@LSHTM.ac.uk.

Will my taking part in this study be kept confidential?
Yes. All the information about your participation in this study will be kept confidential. You will be allocated a unique study number which will be used on data taken outside of the hospital. The study is being run by the Clinical Trials Unit at the London School of Hygiene and Tropical Medicine. Data will be stored on a secure database maintained by the Clinical Trials Unit at the London School of Hygiene and Tropical Medicine. Your name, date of birth or any other identifying information will not be stored on this database with the exception of your NHS Number. Researchers working at [INSERT LOCAL SITE], the University of Oxford, and the London School of Hygiene and Tropical Medicine will have access to the data stored in the database.

Responsible members of the University of Oxford, the Clinical Trials Unit ad London School of Hygiene and Tropical Medicine and [INSERT LOCAL TRUST NAME] may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

What if relevant new information becomes available?
Sometimes during the course of a research study, new information becomes available about the treatment that is being studied. If this happens, a member of the research team will tell you about it and discuss whether you want to continue with the study. If the study is stopped for any other reason you will be told why.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Contact details can be found at the end of this information sheet.

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact the Chief Investigator, Professor Rajesh Kharbanda (contact details at the end of this document) or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email ctrg@admin.ox.ac.uk.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

If you wish to contact the PALS team please contact [INSERT LOCAL DETAILS].

What will happen to the results of the research study?
The results of this study will be reported in medical journals and/or in medical meetings. It will not be possible for individuals to be identified in any publication. De-identified data may also be made available for use in further research, and information about the performance of CEP may be provided to the manufacturer.

A summary of the results will be published on the trial website: bhfprotect-tavi.lshtm.ac.uk. You can also contact the researchers at the details below to request further information.

Who is organising and funding the research?
The University of Oxford is sponsoring this study and it is being run in collaboration with the London School of Hygiene and Tropical Medicine. The study is funded by a charity called the British Heart Foundation. A company called Boston Scientific has provided funding to cover the costs of the Sentinel CEP device.

Who has reviewed the study?
All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the [INSERT NAME] Research Ethics Committee.

Further information and contact details

Investigator's name: (please fill in local details)
Phone number: (please fill in local details)

Study Coordinator's name: (please fill in local details)
Phone number: (please fill in local details)
Chief Investigator's name: Prof Rajesh Kharbanda
Email: bhfprotect-tavi@LSHTM.ac.uk