

# The role of cerebral embolic protection in preventing strokes and improving other health outcomes in patients receiving a replacement heart valve

<b>Submission date</b> 26/02/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 23/06/2020	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/01/2026	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

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.

### Who can participate?

Patients aged 18 years or above, with aortic stenosis planned for treatment by TAVI.

### What does the study involve?

In this study, patients who agree to take part (this means given written consent) receiving TAVI will be randomly assigned to receive CEP during TAVI or to the current standard of care without CEP. Potential participants will be approached prior to their TAVI procedure to discuss the trial.

### What are the possible benefits and risks of participating?

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%. If you are in the group receiving CEP, the time for this radiation would be extended by 10 minutes.

Where is the study run from?

This study is run by University of Oxford (UK) in collaboration with the London School of Hygiene and Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?

April 2020 to December 2025

Who is funding the study?

1. British Heart Foundation (UK)
2. Boston Scientific Corporation (USA)

Who is the main contact?

Zahra Jamal, bhfprotect-tavi@LSHTM.ac.uk

## Contact information

### Type(s)

Public

### Contact name

Dr Zahra Jamal

### Contact details

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London School of Hygiene and Tropical Medicine  
London  
United Kingdom  
WC1E 7HT  
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## Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## Integrated Research Application System (IRAS)

276396

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

PID14772-SP001-AC001

# Study information

## Scientific Title

British Heart Foundation Randomised Trial of Routine Cerebral Embolic Protection in Transcatheter Aortic Valve Implantation

## Acronym

BHF PROTECT-TAVI

## Study objectives

Does the routine use of the Sentinel Cerebral Embolic Protection device during TAVI reduce stroke incidence?

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 23/04/2020, Wales Research Ethics Committee 5 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0)7970 422139; wales.rec5@wales.nhs.uk), ref: 20/WA/0121

## Study design

Prospective multicentre randomized controlled trial

## Primary study design

Interventional

## Study type(s)

Prevention

## Health condition(s) or problem(s) studied

Aortic stenosis

## Interventions

Current interventions as of 04/10/2024:

The study is an RCT evaluating use of the cerebral embolic protection device (Sentinel, Boston Scientific) in participants with aortic valve stenosis planned for treatment by Transcatheter Aortic Valve Implantation (TAVI).

Participants will be randomised 1:1 into a treatment cohort using the cerebral embolic protection device (Sentinel, Boston Scientific) or a control cohort with no cerebral protection system. Enrolled participants will be followed through 72 hours (or hospital discharge), whichever comes first, and assessed for the primary outcome.

Consented patients will be randomised at a 1:1 ratio to either the control or intervention arm before their TAVI procedure. This will be done using a secure online randomisation service.

The intervention group will have TAVI performed with CEP. The Claret Sentinel dual-filter device (Boston Scientific, MA, USA) is a single use, embolic protection catheter inserted into the right radial or brachial artery. This is the only device currently approved for clinical use in both Europe and the USA. The device employs two filters (nitinol frames with 140-micron pores polyurethane film), one delivered to the brachiocephalic artery (Proximal Filter), and one to the left common carotid artery (Distal Filter) before TAVI. Following the TAVI procedure the system is removed.

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Previous interventions:

The study is an RCT evaluating use of the cerebral embolic protection device (Sentinel, Boston Scientific) in participants with aortic valve stenosis planned for treatment by Transcatheter Aortic Valve Implantation (TAVI).

Participants will be randomised 1:1 into a treatment cohort using the cerebral embolic protection device (Sentinel, Boston Scientific) or a control cohort with no cerebral protection system. Enrolled participants will be followed through 72 hours (or hospital discharge), whichever comes first, and assessed for the primary outcome.

Consented patients will be randomised at a 1:1 ratio to either the control or intervention arm at the time of the their TAVI procedure. This will be done using a secure online randomisation service.

The intervention group will have TAVI performed with CEP. The Claret Sentinel dual-filter device (Boston Scientific, MA, USA) is a single use, embolic protection catheter inserted into the right radial or brachial artery. This is the only device currently approved for clinical use in both Europe and the USA. The device employs two filters (nitinol frames with 140-micron pores polyurethane film), one delivered to the brachiocephalic artery (Proximal Filter), and one to the left common carotid artery (Distal Filter) before TAVI. Following the TAVI procedure the system is removed.

## **Intervention Type**

Device

## **Phase**

Phase III

## **Drug/device/biological/vaccine name(s)**

Cerebral embolic protection device (Sentinel, Boston Scientific)

## **Primary outcome(s)**

Current primary outcome measure as of 20/02/2025:

The incidence of stroke at 72 hours post-TAVI, or hospital discharge (if sooner). Events will be validated by an independent clinical events committee blinded to trial treatment.

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Previous primary outcome measure as of 04/11/2021:

The incidence of stroke at 72 hours post-TAVI, or hospital discharge (if sooner). Events will be assessed by the local stroke team and validated by an independent clinical events committee blinded to trial treatment.

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Previous primary outcome measure:

The incidence of all stroke within 72 hours (or hospital discharge) of the TAVI procedure, measured using patient records

## **Key secondary outcome(s)**

Current secondary outcome measures as of 04/10/2024:

1. Combined incidence of all-cause mortality or non-fatal stroke at 72 hours post-TAVI or hospital discharge (if sooner)
  2. Combined incidence of all-cause mortality, non-fatal stroke or transient ischaemic attack at 72 hours post-TAVI or hospital discharge (if sooner).
  3. Incidence of all-cause mortality at 72 hours post-TAVI or hospital discharge (if sooner)
  4. Win ratio for all-cause mortality, disabling stroke and non-disabling stroke at 72 hours post-TAVI, or hospital discharge (if sooner)
  5. Incidence of all-cause mortality at 12 months post-TAVI.
  6. Incidence of all-cause mortality up to the end of the trial. This will use trial data up to 12 months, and centrally held NHS data from 12 months to the end of the trial
  7. Incidence of stroke as defined by centrally held NHS data between 72 hours post-TAVI or hospital discharge (if sooner) and 30-days post-TAVI.
  8. Incidence of stroke as defined by centrally held NHS data between 30-days post-TAVI and the end of the trial.
  9. Stroke Severity: Assessed using the National Institutes of Health Stroke Scale (NIHSS) in participants who have had a stroke within 72-hours post-TAVI or hospital discharge (if sooner)
  10. Disability Outcome Assessed using the Simple Modified Rankin Scale questionnaire (smRSq) up to 12 months post-TAVI in participants who have had a stroke within 72-hours post-TAVI or hospital discharge (if sooner)
  11. Cognitive Outcome Assessed using the standardised Montreal Cognitive Assessment (MoCA) up to 12-months post-TAVI.
  12. Vascular access site related complications (VARC-2 criteria) at 72-hours post-TAVI or hospital discharge (if sooner) and between 6-8 weeks post-TAVI
  13. Cost-effectiveness analysis at 12 months
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Previous secondary outcome measures as of 05/01/2024:

1. Combined incidence of all-cause mortality or non-fatal stroke at 72 hours post-TAVI, or hospital discharge (if sooner)
2. Combined incidence of all-cause mortality, non-fatal stroke and transient ischaemic attack at 72 hours post-TAVI or hospital discharge (if sooner)
3. Incidence of all-cause mortality at 72 hours and 12 months post-TAVI
4. Incidence of stroke as defined by centrally held NHS data between 72 hours post-TAVI (or discharge from hospital, if sooner) and 30-days post-TAVI
5. Incidence of stroke as defined by centrally held NHS data between 30-days post-TAVI and the end of the study
6. Stroke severity assessment in participants who have had a stroke within 72-hours post-TAVI or hospital discharge (if sooner) measured using NIHSS
7. Cognitive outcomes measured using the Montreal Cognitive Assessment up to 12 months post-TAVI
8. Disability outcomes in participants who have had a stroke up to 72 hours post-TAVI or discharge if sooner measured using simple modified Rankin Scale questionnaire up to 12 months post-TAVI
9. Vascular access site and access related complications according to standard criteria defined by the Valve Academic Research Consortium (VARC-2) at 72-hours post-TAVI or hospital discharge (if sooner) and between 6-8 weeks post-TAVI
10. Cost-effectiveness analysis using the EQ-5D-5L and data on resource utilisation at 12 months post-TAVI

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Previous secondary outcome measures as of 29/11/2022:

1. Combined incidence of all-cause mortality or non-fatal stroke at 72 hours post-TAVI, or hospital discharge (if sooner)
2. Incidence of all-cause mortality at 72 hours and 12 months post-TAVI
3. Incidence of stroke as defined by centrally held NHS data between 72 hours post-TAVI (or discharge from hospital, if sooner) and 30-days post-TAVI
4. Incidence of stroke as defined by centrally held NHS data between 30-days post-TAVI and the end of the study
5. Stroke severity assessment in participants who have had a stroke within 72-hours post-TAVI or hospital discharge (if sooner) measured using NIHSS
5. Cognitive outcomes measured using the Montreal Cognitive Assessment up to 12 months post-TAVI
6. Disability outcomes in participants who have had a stroke up to 72 hours post-TAVI or discharge if sooner measured using simple modified Rankin Scale questionnaire up to 12 months post-TAVI
7. Vascular access site and access related complications according to standard criteria defined by the Valve Academic Research Consortium (VARC-2) at 72-hours post-TAVI or hospital discharge (if sooner) and between 6-8 weeks post-TAVI
8. Cost-effectiveness analysis using the EQ-5D-5L and data on resource utilisation at 12 months post-TAVI

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Previous secondary outcome measures as of 04/11/2021:

1. Combined incidence of all-cause mortality or non-fatal stroke at 72 hours post-TAVI, or hospital discharge (if sooner)
2. Incidence of all-cause mortality at 72 hours and 12 months post-TAVI
3. Incidence of stroke as defined by centrally held NHS data between 72 hours post-TAVI (or discharge from hospital, if sooner) and 30-days post-TAVI
4. Incidence of stroke as defined by centrally held NHS data between 30-days post-TAVI and the end of the study
5. Cognitive/disability outcomes measured using the Montreal Cognitive Assessment and simple modified Rankin Scale questionnaire at 72-hours post-TAVI or at hospital discharge (if sooner), and up to 12 months post-TAVI
6. Vascular access site and access related complications according to standard criteria defined by the Valve Academic Research Consortium (VARC-2) at 72-hours post-TAVI or hospital discharge (if sooner) and between 6-8 weeks post-TAVI
7. Cost-effectiveness analysis using the EQ-5D-5L and data on resource utilisation at 12 months post-TAVI

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Previous secondary outcome measures:

Measured using patient records:

1. Combined incidence of all-cause mortality and stroke up to 12 months
2. Incidence of all-cause mortality up to 12 months
3. Cognitive outcomes up to 12 months
4. Vascular access site injury between 6-8 weeks post-TAVI
5. Acute kidney injury between 6-8 weeks post-TAVI
6. Cost-effectiveness analysis

### **Completion date**

04/12/2025

## **Eligibility**

### **Key inclusion criteria**

Current inclusion criteria as of 04/11/2021:

1. Participant is willing and able to give informed consent for participation in the trial
2. Aged 18 years or above
3. Considered to be candidates for TAVI by the clinical team (via any access route where CEP may be used)
4. Participant is suitable for treatment with the cerebral embolic protection device in the opinion of the treating physician

Previous inclusion criteria:

1. Willing and able to give informed consent for participation in the trial.
2. Aged 18 years or above
3. Diagnosed with aortic stenosis (including bioprosthetic valve dysfunction)
4. Planned transfemoral TAVI

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

7635

**Key exclusion criteria**

Current exclusion criteria as of 04/11/2021:

No specific exclusion criteria.

Participants involved in observational studies will be eligible for this study. As this is an all-comer design, current or previous participation in other ongoing randomised trials will not be disqualifying for recruitment to this study unless treatment is expected to impact the effect of using a CEP device on stroke.

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Previous exclusion criteria:

1. Anatomically unsuitable for treatment with the cerebral embolic protection device in the opinion of the treating physician
2. Clinical contra-indications to the use of the CEP device in the opinion of the treating physician

**Date of first enrolment**

29/10/2020

**Date of final enrolment**

09/10/2024

**Locations****Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

Wales

**Study participating centre**

**John Radcliffe Hospital**

Oxford University Hospitals NHS Trust

Headley Way

Headington

Oxford

England

OX3 9DU

**Study participating centre**

**Leeds General Infirmary**

Great George Street

Leeds

England

LS1 3EX

**Study participating centre**

**Royal Sussex County Hospital**

Eastern Road

Brighton

England

BN2 5BE

**Study participating centre**

**New Cross Hospital Royal Wolverhampton**

Wolverhampton Road

Heath Town

Wolverhampton

England

WV10 0QP

**Study participating centre**

**University Hospital of Wales**

Heath Park

Cardiff

Wales

CF14 4XW

**Study participating centre**

**Morrison Hospital**

Heol Maes Eglwys

Cwmrhydyceirw

Swansea

Wales

SA6 6NL

**Study participating centre**

**Royal Infirmary of Edinburgh**

51 Little France Crescent

Old Dalkeith Road

Edinburgh

Lothian

Scotland

EH16 4SA

**Study participating centre**

**St. Bartholomews Hospital**

West Smithfield

London

England

EC1A 7BE

**Study participating centre**

**Kings College Hospital**

Mapother House

De Crespigny Park

Denmark Hill

London

England

SE5 8AB

**Study participating centre**

**Royal Victoria Hospital**

274 Grosvenor Road

Belfast

Northern Ireland

BT12 6BA

**Study participating centre**

**Guy's and St Thomas' NHS Foundation Trust**

St Thomas' Hospital  
Westminster Bridge Road  
London  
England  
SE1 7EH

**Study participating centre**

**Basildon and Thurrock University Hospitals NHS Foundation Trust**

Basildon Hospital  
Nethermayne  
Basildon  
England  
SS16 5NL

**Study participating centre**

**Liverpool Heart & Chest Hospital**

Broadgreen Hospital  
Thomas Drive  
Liverpool  
England  
L14 3PE

**Study participating centre**

**Derriford Hospital**

Derriford Road  
Crownhill  
Plymouth  
England  
PL6 8DH

**Study participating centre**

**Southampton General Hospital**

University of Southampton and University Hospital Southampton NHS Foundation Trust  
Tremona Road  
Southampton  
England  
SO16 6YD

**Study participating centre**  
**Golden Jubilee National Hospital**  
Agamemnon Street  
Clydebank  
Scotland  
G81 4DY

**Study participating centre**  
**Royal Papworth Hospital**  
Papworth Road  
Cambridge Biomedical Campus  
Cambridge  
England  
CB2 0AY

**Study participating centre**  
**St Georges Hospital**  
Blackshaw Road  
London  
England  
SW17 0QT

**Study participating centre**  
**Victoria Hospital (blackpool)**  
Whinney Heys Road  
Blackpool  
England  
FY3 8NR

**Study participating centre**  
**Bristol Heart Institute**  
Lower Maudlin Street  
Bristol  
England  
BS1 2LX

**Study participating centre**  
**Nottingham City Hospital NHS Trust**  
Hucknall Road

Nottingham  
England  
NG5 1PB

**Study participating centre**  
**Hammersmith Hospitals NHS Trust**  
Hammersmith Hospital  
Du Cane Road  
London  
England  
W12 0HS

**Study participating centre**  
**Freeman Road Hospital**  
Freeman Road  
High Heaton  
Newcastle upon Tyne  
England  
NE7 7DN

**Study participating centre**  
**Wythenshawe Hospital**  
Southmoor Road  
Wythenshawe  
Manchester  
England  
M23 9LT

**Study participating centre**  
**Castle Hill Hospital**  
Castle Road  
Cottingham  
England  
HU16 5JX

**Study participating centre**  
**The James Cook University Hospital**  
Marton Road  
Middlesbrough  
England  
TS4 3BW

**Study participating centre**

**University Hospitals Birmingham NHS Foundation Trust**

Queen Elizabeth Hospital

Mindelsohn Way

Edgbaston

Birmingham

England

B15 2GW

**Study participating centre**

**Sheffield Teaching Hospitals NHS Foundation Trust**

Northern General Hospital

Herries Road

Sheffield

England

S5 7AU

**Study participating centre**

**Aberdeen Royal Infirmary**

Foresterhill Road

Aberdeen

Scotland

AB25 2ZN

**Study participating centre**

**Royal Stoke University Hospital**

Newcastle Road

Stoke-on-trent

England

ST4 6QG

**Study participating centre**

**University Hospitals Coventry and Warwickshire NHS Trust**

Walsgrave General Hospital

Clifford Bridge Road

Coventry

England

CV2 2DX

**Study participating centre**  
**Cleveland Clinic**  
33 Grosvenor Place  
London  
England  
SW1X 7HY

## Sponsor information

**Organisation**  
University of Oxford

**ROR**  
<https://ror.org/052gg0110>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
British Heart Foundation

**Alternative Name(s)**  
The British Heart Foundation, the\_bhf, BHF

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Trusts, charities, foundations (both public and private)

**Location**  
United Kingdom

**Funder Name**  
Boston Scientific Corporation

**Alternative Name(s)**  
Boston Scientific, Boston Scientific Corp., BSC

## Funding Body Type

Government organisation

## Funding Body Subtype

For-profit companies (industry)

## Location

United States of America

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		30/03/2025	16/04/2025	Yes	No
<a href="#">Other files</a>	Communication from the BHF PROTECT-TAVI Trial Steering Committee	25/10/2024	28/10/2024	No	No
<a href="#">Participant information sheet</a>	version v1.0	16/03/2020	23/06/2020	No	Yes
<a href="#">Participant information sheet</a>	version 7	29/07/2024	04/10/2024	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol (other)</a>			16/04/2025	Yes	No
<a href="#">Protocol file</a>	version 4.0	17/10/2022	29/11/2022	No	No
<a href="#">Protocol file</a>	version 6	29/07/2024	04/10/2024	No	No
<a href="#">Statistical Analysis Plan</a>			16/04/2025	Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes