

# PARTICIPANT NEWSLETTER

AUGUST 2023



## Welcome to the first BHF PROTECT-TAVI participant newsletter.

Thank you for taking part in this important study. This newsletter will update you on how the research study is progressing.

This research will help us to know whether cerebral embolic protection (CEP) devices are effective at preventing stroke in patients undergoing transcatheter aortic valve implantation (TAVI).

We would also like to let you know about an important change to the data processing arrangements on the trial. This will help us to understand whether the CEP devices are good value for money for the NHS.

The BHF PROTECT-TAVI trial will recruit 7,730 patients in total. Recruitment to the trial started in October 2020 and since then we have recruited over **4700 patients from 31 TAVI centres in the UK.**

Last month, data from the trial was independently reviewed by a Data Monitoring Committee (DMC). This was done to see whether it is safe and ethical for the trial to continue. The DMC recommended that the trial should continue as planned. The DMC will monitor the data again in early 2024. A newsletter will be available on the website after the committee has met.

## UPDATE TO DATA PROCESSING ARRANGEMENTS

We are intending to make a change to our data processing arrangements which was not described in the patient information sheet and consent form.

The University of Oxford and the London School of Hygiene and Tropical Medicine intend to work with the University of York to conduct a health economics analysis for BHF PROTECT-TAVI. This is important work that will allow us to understand how the use of Cerebral Embolic Protection devices impacts the NHS in terms of cost and service use.

What this means is that your routine health records that the University of Oxford and the London School of Hygiene and Tropical Medicine obtained from NHS England will also be shared with researchers from the Health Economics team at the University of York. Access will be strictly controlled, and your data will be in a form that will not contain anything that identifies you personally. The data will be held in a secure database on the server at the London School of Hygiene and Tropical medicine and will be shared virtually with the researchers at the University of York.

As with all aspects of this study, if you have a concern about any aspect of this study, or wish to withdraw from the study at any time, you can do this by contacting the research team at the hospital where you had your TAVI.

**Website:** <https://www.lshtm.ac.uk/research/centres-projects-groups/bhfprotect-tavi>

**Twitter:** @bhfprotect\_tavi