

BHF PROTECT-TAVI Results



Why we did the study

TAVI is a procedure used to treat aortic stenosis, a heart condition where the aortic valve becomes narrow and stiff reducing blood flow from the heart to the rest of the body. During a TAVI procedure, debris from the valve and blood vessels can be released into the bloodstream. This debris can sometimes block the arteries which supply the brain and cause a stroke. This happens in about 2 patients for every 100 that are treated with TAVI.

Cerebral embolic protection (CEP) devices are filters which are placed in the arteries which supply the brain with blood. The CEP devices are designed to prevent strokes by capturing debris before it reaches the brain. BHF PROTECT-TAVI used the Sentinel device, which is a CEP device manufactured by Boston Scientific and is approved for use in Europe and USA.

The BHF PROTECT-TAVI trial was run to test whether using the Sentinel CEP device during TAVI procedures can reduce the risk of stroke.

What we did

Between October 2020 and October 2024:



7,635 patients
having TAVI took
part in the trial

From **33 hospitals**
in the UK

Patients were put into
two groups at random



**Control
group**

3820 patients
who had TAVI
without the
CEP device



**CEP
group**

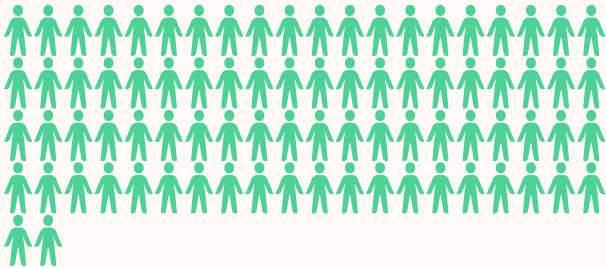
3815 patients
who had TAVI
with the CEP
device

What we found

Control group

82 patients had a stroke

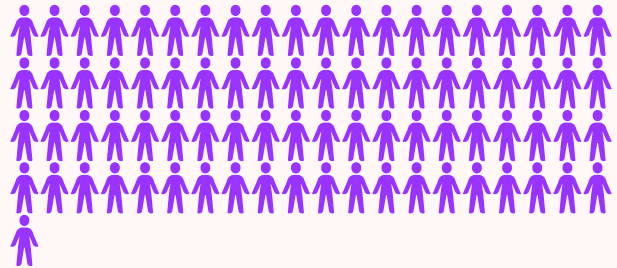
(2.2%)



CEP group

81 patients had a stroke

(2.1%)



The routine use of the Sentinel CEP device during TAVI **did not** reduce the risk of stroke within three days of the TAVI procedure.



The number of patients who **died** within three days of the TAVI procedure was **similar between the groups**



The number of patients who had a **stroke causing disability** up to 8 weeks after the TAVI procedure was **similar between the groups**

What next

The main results of the trial were presented at the American College of Cardiology Conference in March 2025. The findings have also been published in the New England Journal of Medicine.

We are continuing to follow up participants in the trial for a year after their TAVI to see if there are any differences in the health of participants over time. We will share these results with you in spring 2026.

The BHF PROTECT-TAVI trial was funded by the British Heart Foundation and Boston Scientific. The study was sponsored by University of Oxford and managed by the London School of Hygiene & Tropical Medicine.