

Date: 25 October 2024

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

The United Kingdom BHF PROTECT-TAVI Trial is a multi-centre randomised trial of transcatheter aortic valve implantation and cerebral embolic protection (SENTINELTM Cerebral Protection System, Boston Scientific Corporation) versus transcatheter aortic valve implantation alone. The primary outcome is the incidence of stroke within 72 hours, or before hospital discharge (if sooner).

Following an interim analysis of data from 7490 randomised patients, the Data Monitoring Committee determined that there is little prospect of demonstrating a benefit in the primary endpoint and could not rule out potential for harm. The Committee therefore recommended that recruitment into the trial be terminated.

The Trial Steering Committee discussed this recommendation and recruitment into the trial was terminated on 9 October 2024. The trial will now focus on completion of data collection and analysis, with presentation and publication of the trial results in early 2025.