BHF PROTECT-TAVI



INVESTIGATOR MEETING

Thank you to all who attended the Investigator Meeting in November. It was a great turnout and we enjoyed seeing you in-person at last!

API STUDY

Our latest Protocol (v4) includes the API Study. The API Study is an observational, non-randomised study to assess the quality of information given to BHF PROTECT-TAVI trial participants about the trial prior to consent. Data are collected via a self-administered, paper questionnaire completed by trial participants.

The API Study is an optional study open to all BHF PROTECT-TAVI participating sites. If you have any questions about the study, please let us know.

REMOTE CONSENT

Our latest amendment implements remote consent as we know many preoperative appointments are no longer face-to-face. Oral consent (over the telephone or by videoconference) is documented using the approved remote consent form. A Working Practice Document (WPD) for taking remote consent will be sent around soon.

ANIMATION

An animation flyer is now available to use to promote the participant information video, which is available in 5 languages.





STROKES

We have set up a framework in BHF PROTECT-TAVI that maximises the chance to identify participants who may have had a stroke, while fitting in with your usual care pathways.

- Complete the daily QVSFS and encourage the participant to mention any changes they have noticed since the procedure, no matter how trivial they think they are.
- Participants with a normal QVSFS (No to every question) are highly unlikely to have had a stroke. Participants who answer Yes to any of the QVSFS need a clinical decision maker to decide whether further investigations are appropriate, and whether a diagnosis of stroke is likely.
- If in doubt whether a participant has suffered a stroke within 72 hours post-TAVI or before discharge, please complete the Stroke Form in the CRF and provide any available supporting documentation, in particular the time of onset of symptoms.

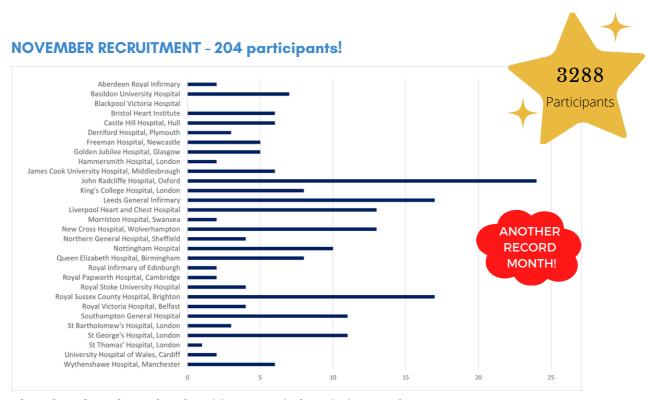


Chart above shows the number of participants recruited per site in November.

CONTACT US

For any queries you may have please email: bhfprotect-tavi@lshtm.ac.uk





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