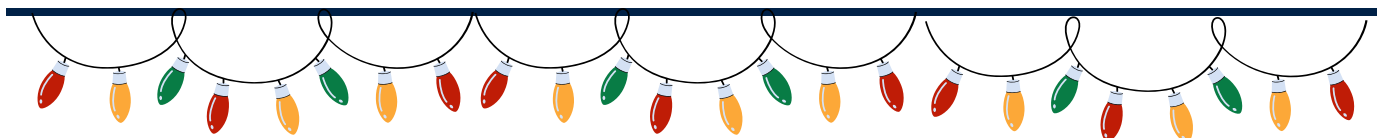


BHF PROTECT-TAVI



As we come to the end of 2022, it is an opportunity to thank you all for your hard work and support of BHF PROTECT-TAVI. Because of your continued dedication, the trial has continued to progress well.

As you will recall, we started recruitment in October 2020. Over the course of 2022 we have opened ten new sites and are now recruiting across 30 of the 33 UK TAVI centres. This is a very positive sign that the trial remains important and is supported by the UK TAVI network. Together, we have recruited over 3300 participants, which means that we have nearly reached our second milestone of 50% recruitment (3865 enrolled). You should be very proud of this progress given the challenges we faced with COVID and the ongoing impact this continues to have on UK research capacity.

Our first interim analysis will be undertaken shortly after the second milestone is met and we anticipate that it will take place in Spring 2023. We need your help to make sure that we have complete and accurate information for the interim analysis.

The trial oversight committees have continued to meet regularly. They have invested significant time and effort engaging with the study to ensure its success. The Data Monitoring Committee met for the fourth time in October 2022 and the Trial Steering Committee met for the fifth time in December 2022. We are hugely grateful for the contribution of the patient representatives, researchers and clinicians involved, and to Colin Berry and Rob Henderson for their leadership of these committees.

Over the last year, we have worked to improve the trial in response to your feedback. We have withdrawn echo uploading and are working to streamline the process for uploading the CT imaging. Patients can now be consented remotely, and we will pilot the use of participant identification centres at one TAVI site to see if this can help to improve recruitment. Please let us know if there are other challenges and we will work with you to try to find solutions.



One of the highlights this year was our first face-to-face investigator meeting in November in London. It was great to see you all in person and have a chance to spend some time together sharing our experiences of the trial and learning from each other.

The results of The PROTECTED TAVR study were presented at TCT in September and we discussed the finding at our meeting last month. Our trial is even more important now and if we continue to recruit actively (many of you have pledged to recruit a minimum of 2 participants per week per site) we can complete our study in good time.

Our other communications continue through the monthly e-bulletin, the trial website and Twitter, and I would encourage you to take a look, and do please let us know what you would like to see in those.

This trial is a huge undertaking and as one of the largest TAVI trials to date, we need to maintain enthusiasm and avoid fatigue. I am sure that we can continue our progress in 2023. November 2022 was our highest recruiting month with 204 participant recruited and if we can maintain that we may reach our third milestone of 5411 participants (70% recruited) by December 2023!!

As we enter the Christmas and New Year season, I know many of you will be working very hard given the present challenges, but I hope that you will be able to take time for personal rest and reflection.

Wishing you all a very happy holiday season with friends and family and with best wishes for a healthy and successful 2023.

Rajesh

