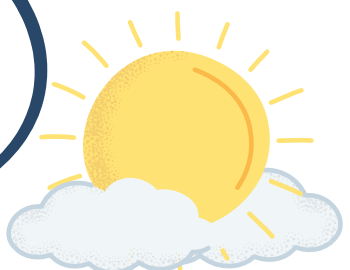




Issue no.16 August 2024



PATIENTS RECRUITED
246
300

THE ROAD TO 300

Welcome to the August issue of the CHIP-BCIS3 newsletter. We hope you are having a lovely summer. **There are now just four months of recruitment remaining!**

July's recruitment progress has been fantastic, with **14 participants** enrolled across **11 different sites**. This means we remain firmly on track to complete recruitment in November. Thank you for your hard work and dedication at this crucial time for the CHIP-BCIS3 trial.

A big congratulations to **St Thomas'** who randomised their **40th** participant in June, **Essex CTC** who randomised their **10th** participant and **QEH Birmingham** who randomised their **25th** participant in July.

We have reset the recruitment leaderboard (below) to showcase the last 6 months of recruitment.



Recruitment Leaderboard June 2024 - present

With just four months of recruitment remaining, we would like to support you in any way we can. Please get in touch with us at CHIP-BCIS3@LSHTM.ac.uk if you have any issues, concerns or any good ideas how we can make life easier for you. We will be delighted to help.



14 randomisations in July 2024

10 randomisations in June 2024



CHIP-BCIS3 Investigators' Meeting on the 4th July

Dr Matt Ryan started the meeting with a trial update. He noted that recruitment is on track, with a boost around the BCIS ACI conference at the start of the year. This has allowed us to extend the sample size to 300 participants. Matt highlighted that although there was an increase to research funding **there was no anticipated change to the overall duration of the trial**. This presents a challenge as we will need to complete recruitment by the end of November, but it is an achievable one.



Professor Jacob Møller was next to speak, presenting a compelling talk on the challenges of delivering DanGer Shock and the reason why they started the study – **to provide more randomised evidence on the use of pLVADs in clinical practice**. The DanGer Shock trial started preliminary as DanShock in 2013, recruiting patients with cardiogenic shock and STEMI only from Denmark.

Jacob reflected on the unexpected challenges of recruiting sufficient numbers into the trial, underestimating the scarcity of eligible patients during DanShock. He noted that after the preliminary study was conducted, they discovered that the vast majority of patients in fact didn't have cardiogenic shock, and only 3% of the population were LV predominant. After filtering out the remaining exclusion criteria, only 1.5% of the population would be eligible. Even with a very high enrolment rate, the investigators' required >25,000 STEMI to randomise 360 patients! These **surmountable challenges in recruitment** meant that the trial expanded to other countries such as Germany (and one site in UK) with support from Abiomed, thereby forming DanGer Shock in 2019, and finally completing recruitment in 2023. He noted **it takes a champion at each of these sites to actively seek and enrol these patients**.

Looking into the data, women showed smaller reduction in mortality compared to men, citing that the underlying reasons may have been the difference in ages (female participants were almost 10 years older than male on average), and time from first onset of symptoms to PCI was twice as long. He noted this is a common issue in a lot of STEMI trials, indicating **an urgent need to improve treatment options for women**. Use of pLVAD was also one of the three independent predictors of an increase in BARC 3-5 type bleeding compared to SOC.

The study did not show routine use in AMI-CS reduced mortality, but there was an effect in a highly selected STEMI population without comatose OHCA and NSTEMI. **Jacob concluded that it was important not to extrapolate the results of DanGer Shock to other populations**.

We extend our thanks to everyone who joined us online and to Professor Møller for giving an inspiring and insightful talk to delivering a challenging and highly impactful trial.

CONTACT US



If you have any questions please don't hesitate to contact the CTU team - Matt Kwok, Megan Knight, Laura Van Dyck and Richard Evans.

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