

Calcium Supplementation for Prevention of Pre-Eclampsia in High Risk Women

CaPE Newsletter - Dec 2023 / 4rd Edition

Welcome to the fourth CaPE newsletter!

Here you'll find messages from the team, tips for best practice and updates on all things trial related, such as recruitment!

Message from the Chief Investigator



Dear CaPE Investigators,

As we come to the end of the year, I wanted to take this opportunity to say a big thank you on behalf of the CaPE trial team for your hard work and support for the study over the year. By the end of this year we'll have opened 32 sites and recruited 495 women in CaPE's, all down to your efforts. A further 24 sites are in various stages of set up, and we continue to approach other sites directly and through the CRN.

We have great news to share from our funder, after our end of pilot meeting with them; HTA has approved an extension to recruitment for the trial until at least September 2024, with another review planned then. They are fully supportive of our plan to open an additional 20 sites, on top of our original target of 40 (total 60 sites), to meet the recruitment targets for this large trial. Moreover, they have agreed for us to provide sites with a per patient payment with more updates to follow.

Don't forget to follow us on Twitter @CaPE trial Lack of availability of the trial medication since November due to delays in procuring the next lot of IMP (with a new expiry date) has been frustrating. We thank you for your patience with this, and for continuing to screen women early in their pregnancy. The good news is that the new batch of IMP will be available to ship to sites from 4th January 2024, so we can hit the ground running in the new year. We will be in touch with you to plan delivery at your individual sites.

The CaPE trial team would like to wish you all a Merry Christmas and Happy New Year, and we hope you have a lovely holiday period. I look forward to touching

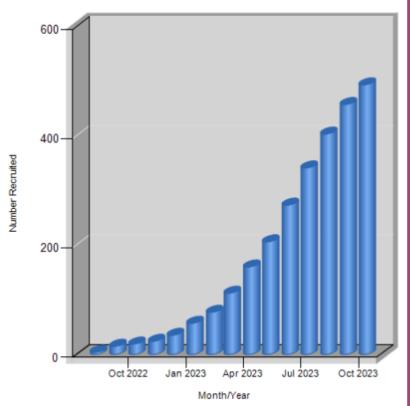
base with all of you in the new year, as we continue to move onwards and upwards with CaPE.

As always, please feel free to contact me by email (smeher@nhs.net), or the trial team (CAPE@trials.bham.ac.uk), or drop in on our fortnightly CaPE Queries online session with any questions or comments. Warm regards, Shireen Meher

Two weekly CaPE Queries online drop in sessions

We host Zoom drop in sessions on the <u>1st Wednesday</u> and <u>3rd Monday</u> of every month where sites can join online to discuss issues, share best practice of just say hi! If you're interested, just please get in touch with the CaPE Team or follow the links provided!

CaPE Recruitment to Date



With IMP expected 4th January 2024, we look forward to picking up where we left off, continuing your excellent recruitment work and setting/breaking more and more recruitment records!

Since the last Newsletter, very well done to the following top recruiting sites!

September

Poole Hospital—7 participants

Royal United Hospital—5 participants

St Richard's Hospital —5 participants

October

Royal London—5 participants

Queen Alexandra—4 participants

BCTU Closure for the Christmas Period

BCTU Closure

From the 21st Dec to the 1st Jan inclusive, BCTU will be closed for the Christmas period. Further, Trial Manager Max Hughes will be available from 8th Jan 2024.

Any reportable SAEs should continue to be reported via the CaPE database, and these will continue to be monitored as usual.

In the rare instance an **Emergency Unblinding** is necessary (i.e., knowledge of trial treatment allocation is essential for clinical management), this can occur locally via the CaPE database - the PI and anyone they've delegated this duty on the DL are able to unblind in this manner. Please see the Randomisation & CRF Completion Guide for details.

If urgent, please contact Max on 07866312007 (though please be aware signal may be intermittent). Alternatively please contact: Bill McKinnon W.McKinnon@bham.ac.uk and Altus Chan z.yenchan@bham.ac.uk

Please contact the BCTU Team if you have any queries

Max Hughes, Trial Manager for CaPE: Email: cape@trials.bham.ac.uk or

Call: +44 (0)121 414 7023 or +44 (0)7866312007 Monday to Friday

New Sites!

Since the last news letter, we're very pleased to welcome on board:

Price Charles Hospital (Cwm Taf)

Princess of Wales Hospital (Cwm Taf)

Southampton General Hospital

Thank-you folks, it's great to have your involvement!

Merry Christmas & Happy New Year!

We really appreciate the hard work and commitment you've shown to the CaPE trial over the past year. You've enabled CaPE's important research question to be offered to an every growing number of participant's who in turn have kindly agreed to take part. Whatever the outcome of CaPE, you are all contributing to the development and understanding of the field of pre-eclampsia, a fantastic and noble cause we hope you are very proud of! We are certainly very grateful!

We look forward to continuing this work with you in 2024, and are excited for what the New Year will bring! In the meantime, we hope this Christmas period is one where you can get some well earned rest, recuperation, and quality time with friends, family and other loved ones—and of course reflect on the successes your hard work has contributed to! Merry Christmas and Happy New Year all, we'll catch you in 2024!



Would you like to appear in the next newsletter? Please get in touch!

Max Hughes, Trial Manager for CaPE: Email: cape@trials.bham.ac.uk or Call: +44 (0)121 414 7023 or +44 (0)7866312007 Monday to Friday