

Consent Form

Local
Trust
Header



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



Chief Investigator: Miss Shireen Meher

Hospital name:

Participant trial number:

PLEASE **TICK** EACH BOX TO CONFIRM CONSENT:

1. I confirm that I have read and understand the CaPE patient information sheet. (Version _ _ , dated _ _ / _ _ _ / _ _ _ _) for the above trial. I have had the opportunity to ask questions, and these have been answered satisfactorily.

Yes No

2. I understand that my participation in the trial is voluntary, and I am free to withdraw at any time without giving a reason why and that my treatment or legal rights will not be affected. Any information up to that point can be used in the study results.

Yes No

3. I agree that my local research team will provide the study organisers at the University of Birmingham a copy of my consent form and some personal information about me and my baby (name, address, date of birth, contact telephone number, ethnicity and NHS number) that is relevant for the study and for any future long term follow up analysis if it is undertaken. My data will be stored at the University of Birmingham.

Yes No

4. I understand that all information collected from me for this study will be subject to the General Data Protection Regulation and Data Protection Act 2018. This information will be stored securely by the University of Birmingham, which is the data controller for the CaPE trial, for a minimum period of 25 years.

Yes No

5. I understand that relevant sections of my medical notes and those of my baby (both paper and electronic) and data collected during the study may be looked at by individuals from the research team, representatives of the sponsor, the University of Birmingham, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have direct access to my records.

Yes No

6. I understand that the information held by the NHS may be used to keep in touch with me and follow up of my status for the purposes of the study.

Yes No

7. I understand that the information collected about me may be used to support other related research in the future, and may be shared anonymously with other researchers.

Yes No

8. I agree that my General Practitioner will be informed about my participation in this trial.

Yes No

9. I understand the information that I have been given about the CaPE trial and I agree to take part.

Yes No

PLEASE **SELECT** THE PREFERRED OPTION:

10. I agree for my contact telephone number (mobile) to be shared with an external organisation (TextLocal) so they may contact me by text message. Any responses I provide will be passed onto the CaPE researchers at the University of Birmingham. I understand that TextLocal will securely delete all the information they hold on me at the end of the CaPE trial.

Yes No

11. I agree that researchers for the CaPE Trial based at my hospital or at the University of Birmingham may contact me for further information by:

Home or Mobile Phone

Yes No

Email

Yes No

Post

Yes No

Other internet call services (e.g. FaceTime / Skype/Zoom)

Yes No

12. I agree to being contacted in the future to ask for my consent to participate in future research related to this study (to see how my baby is developing) and that I may be traced through NHS databases or GP records.

Yes No

Participants Contact Details:

Contact telephone number: *(Auto-populate from randomisation form)*

Email address: *(Auto-populate from randomisation form)*

Internet call service name: (e.g. FaceTime / Skype/Zoom):

Contact number or ID:

Name of Participant:

Signature:

Date: *e.g. 31-JAN-2017 (Auto-populate)*

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Name of Researcher: *(Auto-populate)*

Signature:

Date: *e.g. 31-JAN-2017 (Auto-populate)*

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If completed electronically store a copy in the Site File, 1 copy for participant notes, 1 copy for Participant.

If completed on paper, master copy for Site File, 1 copy for participant notes, 1 copy for Participant, 1 copy for CaPE Trial Office