

***Calcium supplementation for women at high-risk of pre-eclampsia (CaPE)***

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| **Participant Information Sheet** |

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| **We would like to invite you to participate in the CaPE trial.** **This Participant Information Sheet tells you the purpose of the trial and what will happen if you take part.**  |

**Trial summary**

* Pre-eclampsia complicates around 1 in 30 pregnancies every year in the UK. It usually presents with high blood pressure and protein in the urine and may affect other organs in your body.
* The aim of the CaPE trial is to find out whether taking calcium tablets, alongside usual antenatal care, reduces the risk of women developing pre-eclampsia.
* To make sure that it is a fair study, half of the women who take part will receive calcium tablets and the other half will receive dummy (placebo) tablets. The group you are in will be decided by chance and neither you nor your doctors or midwives looking after you will be told which group you are in.
* We will assess to see if there is any difference in developing pre-eclampsia in the group of women who receive calcium, compared to those who receive the placebo tablets without the calcium.
* All women will continue to receive their usual health care during pregnancy.

**What does taking part involve?**

**If you decide to take part:**

* You will need to sign a consent form and answer some questions about your health and diet.
* We will provide you with the trial medication. You will need to take two tablets daily until you have given birth.

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| **Contacts** |
| **Principal Investigator:** <PI Name> |
| **Research Midwife:** <RM Name> |
| **Telephone:** <Number> |
| **Email:** <Address> |
| **Trial Website:** [www.birmingham.ac.uk/CaPE](http://www.birmingham.ac.uk/CaPE)  |

* We will ask you to respond to a text message regarding your trial medication, sent to your phone once a month until birth.

***The CaPE trial has been designed by medical research teams in collaboration with patient groups who have first-hand experience of pre-eclampsia (including Action on Pre-eclampsia Charity).***

1. **Why are we doing this trial?**

Most women with pre-eclampsia generally have good outcomes but some women can become very unwell, with complications affecting the liver, kidneys, and brain. There are also risks for the baby with some needing an early delivery, having problems with growth, and even dying before birth. The CaPE trial wants to look at whether taking dietary calcium supplementation throughout pregnancy lowers the risk of developing pre-eclampsia and its complications.

1. **Why have I been invited to take part?**

You have been invited to take part in the CaPE trial because your maternity team has assessed that you may be at higher risk of developing pre-eclampsia.

1. **Do I have to take part? What if I change my mind?**

Taking part is entirely voluntary and will not affect your current or future NHS care. If you decide to take part but change your mind later, you are free to stop at any time and don’t have to give a reason. Only information you have given up to that point will still be used in the trial results. We would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop.

1. **What will happen if I take part?**

If you do decide to take part in the CaPE trial, you will be asked to sign a consent form to record your agreement to enter the study. We will also collect some information about you (name, date of birth, contact details, ethnicity, and NHS/CHI number), and your calcium intake at the start of the trial and provide you with your trial medication.

Half the women in the trial will receive calcium tablets and the other half a dummy (placebo) tablet. The group you are in will be chosen at random (by chance) by a computer. Neither your maternity team at the hospital, research team, or you, will know which treatment you have received during the trial. However, it will be possible to find out which tablets you have received, if in the rare instance there are any concerns about the safety of the treatment. Regardless of which tablet you are allocated; they will look and taste the same. You will need to take two tablets a day (one in the morning and one in the evening) from the 12th week of pregnancy or the day you start on the trial (no later than 22 weeks of pregnancy), whichever is later, until you have had your baby (or babies). You will be given your full supply of tablets at the start of the trial.

Whilst on the trial we would like to contact you once a month to see how you are getting on with the trial tablets you are taking. We will do this by sending you a text message on your phone with a question you will need to respond to. Alternatively, a member of your research team can go through the question with you on the phone, whichever is easier for you.

To send the text messages, we will be working with a company called TextLocal. TextLocal will be given no further information about you other than your mobile phone number. The answers you provide will be stored by TextLocal and sent only to the CaPE trials team.

With your agreement, we will collect information about your pregnancy and your baby (or babies) from your healthcare records, so that we can answer the trial question.

No additional visits to hospital are required above your standard of care visits. If any new, relevant information about the research or once trial results becomes available, we will ask your local care teams to contact you.

You will not receive any money for taking part in this study.

1. **What are the possible benefits of taking part?**

By taking part in the trial, you may reduce your risk of developing pre-eclampsia and its complications. It is also possible, however, that you may go on to develop pre-eclampsia. Therefore, we do not know whether you will benefit personally from taking part in this trial, but the knowledge gained with your participation will help inform future treatments and potentially lead to improved care for women at risk of pre-eclampsia.

1. **What are the possible disadvantages and risks of taking part?**

The calcium dose you may receive on the trial is not likely to put you or your baby (babies) at risk of experiencing side effects. However as with taking any tablet, there is always a risk no matter how small.

The rare side-effects (affecting less than 1 in 1000 women) reported for calcium are: feeling sick, stomach ache, constipation, diarrhoea, wind, or heartburn. Excessive calcium in your blood or urine can lead to very rare effects (affecting less than 1 in 10,000 women) of skin rashes and itching and kidney stones or other kidney problems. If you would like more information about the side effects listed above, please feel free to discuss this with your medical team.

1. **Can I still take part if I am already taking other medications?**

While on the trial there are some medications which you should not be taking. It is very important you notify your maternity team of any medications you are currently taking. You should avoid other medications that contain calcium or high doses of vitamin D (>1000 IU), as this may lead to large amounts of additional calcium which may increase the risk of side effects. Your medical team will advise you and provide you with written information on which medications you should avoid and examples of alternative medications you can replace them with. For certain other medications you are taking, they may also recommend you change the time in the day you take those medications, as calcium can impact the absorption of some medications.

1. **Who will know about me taking part in this trial?**

We will place a note in your pregnancy record so that everyone in the health care team looking after you knows that you are taking part in this trial. With your permission, we will also write to your GP to let them know.

1. **Will my taking part in the study be kept confidential?**

Personal information recorded will be regarded as strictly confidential and will be handled and stored in accordance with GDPR 2018. The only people allowed to look at the information will be the researchers who are running the study at your local hospital and at the University of Birmingham, and the regulatory authorities who check that the study is being carried out correctly.

All information collected by the Sponsor (the University of Birmingham) will be securely stored at the Study Office at the Birmingham Clinical Trials Unit, University of Birmingham on paper and electronically and will only be accessible by authorised personnel associated with the study. The only people in the University of Birmingham who will have access to information that identifies you will be people who manage the study or for monitoring and audit purposes. When you are entered into the study we will collect your name, address, date of birth, contact telephone number, ethnicity and NHS number. You will be given a unique study number and in routine communication between your hospital and the Study Office, you will only be identified by this study number. A copy of your signed consent will be sent to the Study Office.

What are your choices about how your information is used?

•You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

• If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop.

•We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

For further information about how health researchers use your information please go to: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/>

The University of Birmingham is the sponsor for this study based in the United Kingdom and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. More information can be found on the privacy notice on the trial website: [trial website URL]

All trial data will be looked after by the University of Birmingham and stored securely for 25 years after the end of this trial. With your permission, data may be used to support other related research in the future, and may be shared anonymously with other researchers.

1. **More information about this trial**

**Who funded this trial?**

This trial is funded by the Health Technology Assessment (HTA) and the National Institute for Health and Research (NIHR). <https://www.nihr.ac.uk/explore-nihr/funding-programmes/health-technology-assessment.htm>

**Who runs this trial?**

The Chief Investigator for this trial is Dr Shireen Meher at Birmingham Women’s and Children’s NHS foundation trust. She is running this trial with the Birmingham Clinical Trials Unit, University of Birmingham.

**Who reviewed, gave permission to do this trial?**

This trial is sponsored by the University of Birmingham and has been reviewed and approved by the *[Research Ethics Committees name]* Research Ethics Committee.

**What if I have a problem or concern?**

If you have any concerns about any aspect of this trial, please ask a member of the CaPE trial research team or contact the trial manager (details below).

**What if I have a complaint?**

If you wish to formally complain about any aspects of this trial, you can do this through the Patient Advice and Liaison Service (PALS) *[local PALS details]* that can provide support for any complaints or queries you may have regarding the care you receive as an NHS patient. NHS indemnity covers all clinical treatment provided.

In the unlikely event that you are harmed as a direct consequence of taking part in this trial the University of Birmingham have insurance in place which provides cover to the University for harm which comes about through the University’s, or its staff’s, negligence in relation to the design or management of the trial and may alternatively, and at the University’s discretion provide cover for non-negligent harm to participants.

**Trial managers contact details**

For any additional trial information please contact the trial manager by:

Email: Cape@trials.bham.ac.uk , Tel: [*insert telephone number]*

**Further information**

To access an electronic copy of this patient information sheet and additional information regarding data protection please visit the trial website: www.birmingham.ac.uk/CaPE.

Further information on pre-eclampsia can be found on, Action on Pre-Eclampsia (APEC) Charity website: <https://action-on-pre-eclampsia.org.uk/>

1. **Do you have any further questions?**

Please take the time to decide whether you wish to take part in the CaPE Trial. If you have any questions about the trial now or later, feel free to ask your obstetrician or midwife, or the person who is responsible for the CaPE Trial at your hospital. Having read this information sheet, we hope that you will choose to take part in the CaPE Trial.