We would like to invite you to take part in a research study. Before you decide to join, it is important you know why we are doing this research and what it involves. Read the information carefully and talk about it with your friends or family if you want. Please ask if you have questions or if you would like more information.

What is the purpose of this study?

We are trying to find better ways to reduce the number of pregnant women and babies who die or get very sick from a condition called preeclampsia. Preeclampsia is common worldwide but tends to be more severe in places with limited healthcare resources. It is one of the leading causes of maternal death.

Preeclampsia causes high blood pressure in pregnancy and protein in the urine. It can also damage organs like the liver, kidneys, and brain. For the baby, it may cause poor growth in the womb, early birth or even death. This happens because preeclampsia affects the placenta, which connects the baby to the mother and supplies nutrients and oxygen.

This study is designed to find out whether delivering the baby earlier—between 34 and 37 weeks (around 7.5 to 8.5 months) —reduces health risks for the mother and baby, when pre-eclampsia has been confirmed with a blood test called placental growth factor test (PlGF) that helps diagnose pre-eclampsia compared to waiting until 37 weeks unless an emergency occurs. The results may help improve care for women with preeclampsia in the future.

Why have I been invited to take part?

You have been invited because you are pregnant, and your doctor or midwife thinks you may have preeclampsia, but your condition is not so serious that you need to be delivered immediately.

Do I have to take part?

Taking part is completely up to you. If you choose not to join, your care will stay the same. You can also leave the study at any time, even after you've agreed, without giving a reason.

What will happen if I agree to take part?

You will sign a consent form that confirms you understand the aim of this study and agree to participate (you will be given a copy of the signed consent form). You will then be randomly placed into one of two groups using a computer: **PlGF and Planned Early Delivery Group** or **Usual Care Group**. This means you have a 50/50 chance of being in either group.

- If you are in the **PlGF and Planned Delivery Group**: you will take a PlGF test.
    - **If the blood test is abnormal and confirms pre-eclampsia,** delivery will be started within 48 hours - either labour will be started (induced) or by Caesarean birth (if there is an indication for Caesarean birth). You may receive two steroid injections to help your baby's lungs develop. Labour will be started using a hormone medication. The delivery and steroid injections will be conducted as standard hospital care. After the birth, both you and your baby will receive standard hospital care.

- **If the blood test is normal, and pre-eclampsia is ruled out,** we will recommend you continue your pregnancy until you go in to labour, or another reason for delivery develops. Both you and your baby will receive standard hospital care.

- If you are in the **Usual Care Group**: both you and your baby will receive standard hospital care. You will be monitored closely until delivery. Delivery will be started early if there are problems detected. If necessary, early delivery may still happen. You will still be included in the study if this happens. After the birth, both you and your baby will receive standard hospital care.

Whichever group you are in, your pregnancy outcome data will be recorded; data collected will include outcome data relating to the pregnancy, such as how your baby was born, your baby's birthweight, and any pregnancy complications, collected from medical records.

You will also be asked to fill out a health questionnaire before birth and again at 1 and 6 months after delivery.

What does the blood test involve (in the PlGF Group)?

A small blood sample (about one teaspoon) will be taken from your arm. The process only takes a few minutes. No blood will be taken from your baby. The results will be shared with you and your doctor.

What are the benefits of taking part?

By taking part, you will help us learn if PlGF and planned early delivery improves outcomes for mothers and babies with preeclampsia. This could help improve care for other women in the future. There is no payment for taking part.

What are the risks?

There are possible risks and benefits for both groups; **PlGF and Planned Delivery Group**: Your baby may be born up to 3 weeks early. Early birth may cause breathing issues or require extra care. **Usual Care Group:** If your condition worsens, you or your baby may become very ill. Your medical team will be monitoring you and your baby routinely, and if there are any concerns, then earlier delivery may be recommended.
We do not yet know which option is better, which is why we are doing this study.

What if new information becomes available?

If new information becomes available that is likely to affect your participation in the study, we will discuss this with you, and you will be free to decide whether to continue with the study. If the study is stopped for any reason, we will tell you and let you know what will happen next.

What if I decide to leave the study?

You can leave the study at any time by contacting us. If you withdraw before (insert date), we can delete your data. After that, your records cannot be identified or removed.

What if something goes wrong or I have a complaint?

Please talk to the research team if you have concerns. For formal complaints, contact:
The Chair, Health Faculties Research Ethics Sub-Committee, King's College London, UK.
Email: rec@kcl.ac.uk

Will my information be kept private?

Yes. A note will be added to your medical records. Your personal data will be kept confidential, securely stored for up to 25 years, and labelled with a code. Data is stored by OMDA. More info: https://omadaidentity.com/company/privacy-policy/. Only approved researchers will access your data including local research staff and researchers from King's College London. Data collected will include outcome data relating to the pregnancy, collected from medical records. All shared results will be anonymous. Data will be processed in line with the Data Protection Act 2018 and UK General Data Protection Regulations (UK GDPR), as well as local national data protection laws.

What happens after the study?

We may ask for your permission to use your data in future approved research. This may involve other research partners.

What will happen to the results?

Results may be shared in reports and conferences, but your identity will remain confidential. If you'd like to know when results are published, ask the research team.

Who is organising and funding the research?

This study is led by King's College London and funded by the National Institute for Health and Care Research (NIHR).

Who approved the study?

The study has been reviewed and approved by ethics committees both locally and at King's College London.

What if I have more questions or want to take part?

Contact your local research team. For emergencies or health concerns, please speak to your midwife or doctor.

Thank you for thinking about joining the PAPAGAIO Project!
Your help is important to improve the health of pregnant women and their babies around the world.

Contact the PAPAGAIO team: papagaio@kcl.ac.uk