

Participant Information Sheet

LOCAL HOSPITAL HEADER



PRISM: PROGESTERONE IN EARLY PREGNANCY BLEEDING

LOCAL RESEARCH TEAM

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PRISM: PROGESTERONE IN EARLY PREGNANCY BLEEDING

PARTICIPANT INFORMATION SHEET

We would like to invite you to take part in a research study. Whether you take part or not is entirely your choice. You do not have to take part, nor give a reason why you decide not to. If you decide not to take part, this will not affect the care you are receiving from your doctors. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

Our study will investigate whether progesterone, a natural pregnancy hormone, could help to reduce the risk of miscarriage for women with bleeding in early pregnancy. We will compare the experiences of women who take progesterone with the experiences of women who take a dummy (placebo) treatment.

This information sheet tells you the purpose of the study and explains what will happen if you take part. Please ask us if there is anything that is not clear or if you would like more information.

If you decide to participate in our study you will be given a copy of this information sheet and a signed consent form to keep.

Thank you for considering participation in the PRISM study.

PRISM

PROGESTERONE IN EARLY PREGNANCY BLEEDING

What is the purpose of the study?

Pregnancy is a life-changing experience, both physiologically and psychologically. Unfortunately as many as one in five pregnancies end in miscarriage. The purpose of this study is to find out whether progesterone, a natural pregnancy hormone, can help to reduce the risk of miscarriage for women with bleeding in early pregnancy (up to 12 weeks). At the moment we do not know if progesterone helps to reduce the risk of miscarriage or not, but previous small studies show that it may be helpful.

Why have I been invited to take part?

You have been invited to take part in the study because you have experienced bleeding in the first 12 weeks of your pregnancy. We plan to recruit 4150 participants from hospitals around the UK.

Do I have to take part?

Participation in our study is entirely voluntary. If you decide to take part, you will be asked to sign a consent form. If you do not wish to take part, you will not have to give a reason and your decision will not affect the care you will receive. Similarly, if you do decide to take part, you will be able to withdraw from the study at any time and without giving a reason, and without any effect on the medical care or maternity care that you receive.

If I take part, will I have progesterone or placebo?

Neither you nor your doctor or nurse will be able to choose which treatment you receive. Your place in the progesterone group or the placebo group will be decided by a computer at the PRISM Trial Office. The computer will allocate treatment randomly, like tossing a coin. You will have an equal chance of receiving the progesterone treatment or the placebo treatment. In addition, neither you nor your doctor or nurse will know your allocation to the progesterone group or the placebo group throughout the study. This method of research is called a “double blind randomised controlled trial”.

How do I take the trial treatment?

A nurse will arrange for the study treatments to be dispensed to you. You will receive oval capsules about the size of a baked bean, to be inserted into your vagina. The capsules are not to be swallowed. You will be told how to insert them into your vagina with your fingers (rather like using a tampon). Alternatively, if you prefer, then you will be able to use the capsules as suppositories (inserting them into the rectum). It will be necessary for you to insert two capsules (either vaginally or rectally) twice daily. You will insert two in the morning and two at bedtime, from the time that you receive them until 16 weeks of pregnancy. We will give you enough capsules to last until 16 weeks of pregnancy.

What else will I have to do?

This study will fit into your usual antenatal care, so that you will not have to make any extra hospital visits. If you decide to take part in the study, the only requirement will be for you to keep the vaginal capsules that we give to you in a safe place, and to insert two vaginal capsules in the morning and two vaginal capsules in the evening until 16 weeks of pregnancy.

We will collect most of our study information about your pregnancy and your baby from your hospital notes but we may need to contact you to check some details.

Please tell us if you would prefer to be contacted by phone or email. We would also like to contact you after your participation in the study has ended, to ask your permission to follow up the effects of the study for you and your baby in the long term.

What are the benefits of taking part?

We do not know whether you will benefit personally from taking part in this study, but the knowledge gained thanks to your help will inform future treatment and potentially lead to improved antenatal care and pregnancy outcomes for women in the future.

What are the risks of taking part?

Previous studies using progesterone treatment during pregnancy have found very little evidence of risks for the mother or the baby. However, some women may experience swollen hands or feet, bloating, headache, sleeplessness, diarrhoea or jaundice. If you have any concerns, please contact the people named on the first page of this information sheet. If you become unwell during your pregnancy, seek medical help. We will give you a card to carry and give to anyone treating you, informing them that you are taking part in the PRISM Trial.

What if new information becomes available?

Sometimes new information about medicine becomes available. If this happens, we will tell you and discuss whether you should continue in the study. If you decide not to carry on with the study then we will make arrangements for your care to revert to standard care. If you decide to continue in the study then we may ask you to sign an updated consent form.

If the study is stopped for any other reason, we will tell you and arrange your continuing care.

Can I decide not to carry on with the study?

If you decide to take part in the study but then change your mind, you will be free to withdraw at any time and stop taking the study treatment, without giving a reason (although we will appreciate it if you tell us why you change your mind). Your maternity care will not be affected in any way.

If you decide to stop the treatment, we would still like to find out what happens to you during your pregnancy, and to use all the information already collected from you, unless you tell us that you are unwilling for us to do so.

Will my participation remain confidential?

All the information collected in the PRISM study will be handled strictly in accordance with your consent and the Data Protection Act 1998. If you decide to participate in the project, your doctor may send basic information about you to the study organisers at the University of Birmingham. All the information will be held securely and in strictest confidence, and used only for research purposes. You will not be identified in any published results of the study.

Occasionally, inspections of clinical study data are undertaken by statutory regulators, to verify the quality of the research. But otherwise, only authorised members of the research team will have access to any information collected from you.

At the end of the study your data will be archived in accordance with Research Governance Framework guidelines and the NHS Trust policy of your participating centre.

How will my GP know I am participating?

With your consent, we will inform your General Practitioner of your participation in the study.

What will happen to the results of the study?

When the results of the study are known, we will inform you of the overall findings by email and via our website. We will also publish the overall findings of the study in medical journal(s), for consideration by the National Institute for Health and Clinical Excellence (NICE).

Who has organised and reviewed the research?

This study has been funded by the National Institute for Health Research (NIHR). It is organised, managed and coordinated by the University of Birmingham, and data will be collected and stored by this institution. The study is sponsored by the University of Birmingham.

The PRISM project has been reviewed by the South-Central Oxford C Research Ethics Committee. Additionally, the study will be supervised on a regular basis by a Data Monitoring Committee (DMC) and a Trial Steering Committee (TSC). The primary function of the DMC is to ensure the absolute safety of all participants in the project.

The doctors and nurses caring for you will not receive any payments or other benefits for recruiting women into the study. Our study participants will not be paid either, but they will be greatly appreciated, and they will be important in finding out more about how to prevent miscarriage.

What if there is a problem?

If you take part in the project, then you will retain the same legal rights as any other patient within the National Health Service. If you are not satisfied with any aspect of the way in which you have been approached or treated during the course of our study, then please speak first to the researchers (our contact details are on the front cover of this information sheet).

If you wish to complain formally, then the normal National Health Service complaints mechanisms will be available to you: please ask to speak to the Patients Advisory and Liaison Service (PALS) Manager for the Hospital.

Where can I find more information?

If you have any questions about the study now or later, please feel free to ask the nurse or doctor named on the front page.

The UK Clinical Research Collaboration has produced a guide entitled, 'Understanding Clinical Trials'. This leaflet can be downloaded from their website: www.ukcrn.org.uk and could be useful if you are interested in learning more general information about clinical research.

Thank you again for taking time to read this information sheet and for considering taking part in the PRISM study.