

Platform Randomised Trial of Treatments in the Community for Epidemic and Pandemic Illnesses: The PRINCIPLE Trial

PREGNANT PARTNER INFORMATION LEAFLET

The purpose of this information sheet is to explain why we would like to follow the progress of your pregnancy. The information provided in this information sheet will help you decide if you are willing to agree to this. Please take the time to read this information carefully, and discuss with others if you wish. Please ask if there is anything that is not clear, or if you would like more information.

Why we would like to collect information on your pregnancy:

Your partner has been taking part in a research study called PRINCIPLE. The PRINCIPLE trial is investigating potential treatments for COVID-19 in adults aged 18 and over, who have a positive test for COVID-19 and symptoms of COVID-19 illness. As part of this trial, your partner was taking a medication called Favipiravir. Your partner was advised to use highly effective contraception for the 28-day duration of the trial because the effects of the study drug on pregnancy and the developing foetus are not known.

Your partner has reported that you became pregnant while he was enrolled on this trial. We would like to ask your permission to follow your pregnancy to collect some information on you and your baby that will help us understand more about the study treatment. Information collected from you will help our understanding of the effects and safety of the trial treatment.

Voluntary Participation:

Your participation is entirely voluntary. You may refuse at any time. You may decide not to allow the collection of information on your pregnancy, or you may decide to allow it and then change your mind.

Refusal to participate will not result in any penalty or loss of rights/medical care to which you or your partner are otherwise entitled. If you decide to withdraw after providing some information, we will only keep the information collected up to that point.

What information will I need to supply?

The researchers will collect information from you on your pregnancy. This may be throughout your pregnancy, once your baby is born and for some time (up to 28 days) after the birth. If you consent to allow the researchers to record specific information about the pregnancy, the type of information requested will be as follows:

- How and when the pregnancy was confirmed and conceived
- Expected delivery date
- Your medical history (if relevant to your health during pregnancy/your baby's health)
- A history of previous pregnancies
- Any medications you may have taken since you became pregnant
- Any procedures you have received (for example X-rays or surgery) since becoming pregnant

Information on the progress and outcome of the pregnancy will be recorded by the researcher at a later date.

What are the possible risks and discomforts of supplying this information?

We do not know what effect (if any) the trial treatment that was given to your partner may have on pregnancy and the developing foetus. You and your baby will be monitored by doctors as you would normally. There are no additional medical risks to you or your unborn baby from allowing us to follow your pregnancy. We will only collect information from routine assessments of yourself and your baby.

What are the possible benefits of supplying this information?

There will be no direct benefit to you by allowing us to follow the progress of your pregnancy. However, you may help scientists better understand the effects of your partner's exposure to the trial treatment during pregnancy.

Will my information be kept confidential?

Your partner was assigned a study number when he entered the trial. Researchers use this number to keep track of information. To protect your privacy, any information collected about your pregnancy will not be linked to your name or your partner's name and will only be recorded using the study number that has been assigned to your partner. Your partner's study doctor and the trial staff will keep the link between your partner's subject number and your name. Your child's name will not be collected.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest'. The University of Oxford is the data controller for this study and is responsible for looking after your information and using it properly. A privacy notice is on the trial website www.principletrial.org/participants/how-to-join-the-trial#further-information. The study team will keep identifiable information about you for 6-12 months after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Oxford for a maximum of 20 years after the end of the study.

Information collected about your pregnancy will only be seen by the researchers and by other groups involved in the study that your partner is participating in. This may include staff at Oxford University, research ethics committees (RECs), and regulatory authorities who check that the trial is being carried out correctly. As detailed above the information collected will be anonymous, it will also be stored securely. After the trial ends the information held in your medical records will be stored according to local NHS trust policies.

We will also inform your GP that we are collecting information about your pregnancy. By signing the consent form (if you choose to do so), you will allow information related to your pregnancy to be seen by people involved in the study, and for us to contact your GP.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this trial.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this trial, you should contact the trial team on principle@phc.ox.ac.uk or **0800 138 0880** or you may contact the University of Oxford Research Governance, Ethics and Assurance Team (RGEA) office on 01865 616480, or the Head of RGEA on ctr@admin.ox.ac.uk.

Who is organising and funding the study?

Funding has been provided by the UK Research and Innovation (UKRI) and National Institute for Health Research (NIHR). PRINCIPLE has been set up by the Primary Care Clinical Trials Unit at the University of Oxford. In-kind contributions: Department of Health and Social Care provided Favipiravir, free of charge.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee (REC). The REC is there to protect your safety, rights, wellbeing and dignity. This trial has been ethically reviewed and was approved by the South Central - Berkshire Research Ethics Committee (REC Reference: 20/SC/0158).

This trial has also received approval from the Medicines and Healthcare products Regulatory Agency (MHRA).

Further information and contact details:

If you have any questions or concerns, please contact the study team in Oxford on principle@phc.ox.ac.uk or **0800 138 0880**.