basic information about you to the study organisers at the University of Birmingham. Information about you in the form of paper records will also be securely stored at your participating centre. 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 and individuals involved in your direct care will have access to any information collected from you.

At the end of the study your data will be archived for at least 25 years in accordance with Research Governance Framework guidelines and the NHS Trust policy of your participating centre. Once your data has been archived for the required amount of time your data will be securely destroyed.

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/or 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 Care 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 MifeMiso study has been reviewed by the West Midlands—Edgbaston Research Ethics Committee. Additionally, the study will be supervised on a regular basis by a Data Monitoring and Ethics Committee (DMEC) and a Trial Steering Committee (TSC). The primary role of the DMEC is to ensure the absolute safety of all participants in the study.

The doctors and nurses/midwives caring for you will not receive any payments 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 treat miscarriage.

What if there is a problem?

If you take part in the study, 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 leaflet).
If you wish to complain formally, then the normal National Health Service complaints mechanisms will be available to you: please ask to speak to [insert local details of independent advice service as per local trust policies].

Where can I find more information?

If you have any questions about the study now or later, please feel free to ask the nurse/midwife or doctor named on the front page. For more information you can also visit our website at www.birmingham.ac.uk/mifemiso.

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.

Also, the Association of Research Ethics Committees (AREC) www.arec.org.uk publishes a series of online leaflets with more information about medical research that may be of interest to you.

Thank you for taking the time to read this information leaflet and for considering taking part in the MifeMiso study.

OK TO ASK about clinical research

NHS National Institute for Health Research

UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit

LOCAL HOSPITAL HEADER

Patient Information Leaflet

MIFE MISO

A randomised placebo-controlled trial of mifepristone and misoprostol versus misoprostol alone in the medical management of missed miscarriage

Principal Investigator: <insert name>

Lead Research Nurse/Midwife: <insert name>
Telephone: <insert number>
Email: <insert email address>

Trial Coordinator: Leanne Homer
Telephone: 0121 414 9011
Email: mifemiso@trials.bham.ac.uk

MifeMiso Trial
Patient Information Leaflet
IRAS ID: 201600

v3.0 01-Mar-2017
ISRCTN: 17405024

Key summary

Why have I been invited to take part?
You have been invited to take part in this study because you have been diagnosed with a missed miscarriage and you have chosen to have medical management of miscarriage. We plan to recruit 710 participants from hospitals around the UK.

What is the purpose of the study?
The purpose of this study is to test which is the best drug treatment for the medical management of missed miscarriage. In this study, we will test if taking an extra tablet (called mifepristone) in addition to the standard treatment (a drug called misoprostol) is more effective for treating missed miscarriage.

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 that you receive.

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 treatment of miscarriage for women in the future.

What are the risks of taking part?
Mifepristone blocks the action of the hormone progesterone to help speed up the process of miscarriage. As a consequence, you may experience increased vaginal bleeding. All patients who take part will receive misoprostol, which helps your uterus contract to push out the pregnancy tissue and can cause period-like cramps, sickness, diarrhoea and flu-like symptoms.

If you have any concerns, please contact the people named on the front page of this information leaflet. If you become unwell during your treatment, 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 MifeMiso study.

Contact Details:
Thank you for taking the time to read this information. If you have any questions then please feel free to get in touch with us using the contact details on the front of this leaflet.

What is a placebo?

A placebo is a 'dummy' pill that looks like the real drug but doesn't contain any active ingredients. We need to give half the patients this dummy drug so that we can test the benefit of the real drug (mifepristone).

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

Neither you nor your doctor or nurse/midwife will be able to choose which treatment you receive. Your place in the mifepristone group or the placebo group will be decided by a computer at the MifeMiso Trial Office. The computer will allocate the treatment randomly, like tossing a coin. You will have an equal chance of receiving the mifepristone treatment or the placebo treatment. In addition, neither you nor your doctor or nurse/ midwife will know your allocation to the mifepristone group or the placebo group throughout the study. This method of research is called a "double blind randomised controlled trial". Everyone who takes part in the study will be treated two days later with the standard treatment (misoprostol).

What do mifepristone and misoprostol do?

Mifepristone blocks the action of the pregnancy hormone progesterone. This is thought to improve the effect of misoprostol, which makes the womb contract to push the pregnancy tissue out.

How do I take the trial treatment?

You will swallow the first tablet (mifepristone) by mouth whilst you are attending the hospital. You will be given the second tablet (misoprostol) two days later. The route used to administer this treatment will depend on your local hospital's standard procedures. It will either involve taking another oral tablet, or inserting the tablet into your vagina.

What else will I have to do?

This study will fit into your usual care. If you decide to take part in the study, the only requirement will be for you to return to hospital two days later to receive your misoprostol treatment. You will also be required to return to the hospital seven days later to undergo a routine ultrasound scan to check whether your miscarriage has resolved at this stage.

We will collect most of our study information from your hospital notes but we may need to contact you to check some details. We will ask you to complete a short questionnaire (EQ-5D-5L) to record how you are feeling at your hospital visits and upon discharge.

We would also like you to complete a survey at the end of the study that will record your experiences of taking part in the study. You may also be contacted by one of our research team from the University of Birmingham to be interviewed in more depth about your experiences. Please tell us if you would prefer to be contacted by phone, email or post.

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 in the long term.

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 care will not be affected in any way.

If you decide to not take any of the treatment, we would still like to find out what happens to you, 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 MifeMiso study will be handled strictly in accordance with your consent and the Data Protection Act 1998. An external database provider will be used to securely store information about you. The database is a secure online data capture system with restricted access via unique login usernames and passwords. Individual researchers at participating centres will be able to access the data of their own patients only. It uses advanced security systems to protect the personal details of research records. If you decide to participate in the study, your doctor may send