all participants in the study.

What if there is a problem?

If you take part in the MifeMiso Patient Satisfaction interview 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 page 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 contact the researchers named on the front page. For more information you can also visit our website at **www.birmingham.ac.uk/mifemiso**.

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 Patient Satisfaction Interview Study.

OK TO ASK about clinical research

NHS National Institute for Health Research

UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit

Patient Information Leaflet
Patient Satisfaction Interview Study

MIFE MISO

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

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MifeMiso Trial
Patient Information Leaflet
Patient Satisfaction Interview Study
IRAS ID: 201600

v4.0 01-Mar-2018
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 taken part in the MifeMiso Trial and have completed the patient satisfaction survey within the last six weeks. We plan to interview approximately 50 participants from the MifeMiso trial.

What is the purpose of the study?

The purpose of this study is to explore your views on participating in the MifeMiso trial and your satisfaction (or dissatisfaction) with the treatment that you have received following your miscarriage.

Do I have to take part?

Participation in this patient satisfaction interview 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?

This interview study does not involve any treatments or tests. So there is no physical risk involved. Taking part will involve discussing your experiences of participating in the MifeMiso trial and the treatment you have received following your miscarriage. You may find this distressing. If you become upset the researcher will pause the interview to check that you are okay to continue, and if you wish they can move the discussion away from the topic that upset you. If you feel the interview is causing undue distress or emotional discomfort, you can end the interview at any time. If you feel that you need further support, the research team will have the contact details of relevant people to help you (e.g. your research nurse/midwife) and miscarriage charities.

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 will happen if I take part?

You will be invited to take part in a one off interview (informal discussion with a researcher from the University of Birmingham) to explore your experiences of taking part in the MifeMiso trial and of the treatment you have received following your miscarriage. We would like to talk to you within six weeks of your discharge from treatment at a time which is convenient for you. You can choose whether the discussion takes place at the University of Birmingham (if you're local to Birmingham), in your own home, via telephone or via video call software e.g. Skype. This informal one to one discussion will be audio recorded to allow the researcher to pay full attention to what you are saying. Recording the interview will also allow the research team to do further analysis at a later date. Typically, interviews can last between one and one and a half hours, but can take longer depending on how much there is to discuss. Both during and at the end of the interview the researcher will check that you are comfortable and happy with the discussion. If you feel that you need further support after the interview then the researcher will have contact details of relevant people.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time and without giving a reason. A decision to withdraw at any time or a decision to not take part will not affect the standard of care you receive.

If you decide to withdraw you must let us know within two weeks of the date of the interview. After this time, your data will have been anonymised and cannot be withdrawn from the study.

Will my participation remain confidential?

All the information collected in the MifeMiso Patient Satisfaction Interview Study will be handled strictly in accordance with your consent and the Data Protection Act 1998. Very occasionally, interviews bring to light information about a participant which could affect their welfare or the welfare of others. If this happens during your interview then the researcher may need to disclose this information to the relevant authority/ agency. Certain welfare concerns may override concerns about confidentiality.

What will happen to any data I give?

The audio-recording of the interview will be used to produce a typed record of the discussion, known as a transcript. This transcription will be done by a specialist transcription company who will sign an agreement to keep your data confidential and stored securely. We will analyse the anonymised transcripts as part of our research. Your personal data (e.g. your name, address and phone number) will be stored safely at the University of Birmingham and will be safely destroyed when the main results are of the study are published.

At the end of the study your anonymised data will be archived for 25 years in accordance with Research Governance Framework guidelines and the NHS Trust policy of your participating centre. The data you provide will only be accessed by the study team at the University of Birmingham, or by authorised people from the regulatory authorities to check that the study is being carried out correctly.

How will the data be anonymised?

The transcript will be checked carefully for anything that might identify you (e.g. your name, the hospital where you received care) and these details will be removed. Each participant will be given a unique study number and we will only use this to identify quotes in study reports and publications.

Will I be reimbursed for my participation?

We will offer you refreshments and reimburse reasonable travel expenses if you decide to travel to the University of Birmingham for the interview.

What will happen to the results of the study?

When the results of the study are known, we will inform you of the findings by email and/or via our website. The final results of the study will be reported to the funders of the research, and they will be published in appropriate academic and professional journals, and presented at conferences.

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 securely 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