Information from Menstrual Fluid

Participant Information Sheet

You are invited to take part in a research study. To help you decide whether or not to take part, 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. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Clinical researchers and scientists at the University of Edinburgh are carrying out research to better understand gynaecological conditions. The purpose of the study is to determine if there are differences in menstrual fluid and/or the vaginal/womb/gut microbiome (naturally occurring bacteria) between women with heavy periods and normal periods. It is hoped findings from this research will help to develop new ways to non-invasively identify heavy menstrual bleeding and its underlying causes.

Why have I been invited to take part?

You have been asked to take part as you are aged 18-55, have regular periods and are not currently using any hormonal contraception or antibiotics and are not breastfeeding.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?

1. If you decide to take part in our research, it will involve signing a consent form and having a short interview with a member of the clinical research team, to enquire about you and your past and recent health.
2. The research team will arrange to check your blood pressure, height and weight and a urine pregnancy test. We will also ask for a sample of blood (approximately one teaspoon).
3. If you do not have a result available from a pelvic ultrasound in the last 12 months, we will arrange for you to have one performed. This is to identify if there are any structural changes in the womb such as fibroids (a non-cancerous growth in the muscle layer of the womb) or adenomyosis (invasion of the lining of the womb into the muscle layer).
4. You will be asked to collect all the menstrual products (tampons and menstrual pads) used over one period and to provide a sample of menstrual fluid, collected using a menstrual cup. You will also be asked to provide a swab of the menstrual cup before it is used. The equipment and instructions on how to do this will be provided and you will be able to contact the research team if you need any support with this. We will ask you to collect these samples at home and drop them off at the hospital

or collection by the clinical team will be arranged, at a suitable time for you. Ideally, the sample of menstrual fluid should be returned within 4 hours of removing the menstrual cup.

5. You will also be asked to provide self-collected vaginal swabs and stool (poo) samples before and after your period. Written instructions will be provided explaining how to collect these samples at home. These can be returned in pre-paid enveloped provided by the research team.
6. Additionally, there is the option of providing tissue samples from the lining of the womb (endometrial biopsy). This may be part of a routine clinic appointment and/or may involve a separate visit. Taking a sample from the lining of the womb involves an examination similar to a smear test. A thin plastic sampler is passed through the neck of the womb, to take a sample of the lining. The procedure is carried out in the outpatient department and you may wish to take painkillers (e.g. what you would for a headache) 1 hour before the procedure. Local anaesthetic can be requested. A further blood sample will be collected on the same day as the biopsy (approximately one teaspoon).

Participation in this study is optional. Parts 1-4 are the core elements of the study, parts 5 & 6 are optional. If you agree to take part in the study, it may involve up to four visits to the hospital (typically 1 or 2). We will reimburse you for reasonable travel expenses that you incur if study visits are required. The research team will endeavour to make the visits as flexible as possible, however, it is important the completed menstrual fluid collection is returned promptly, ideally within 4 hours. If you agree, we will let your GP know you are participating within the study and let them know any information obtained from the study that may impact your health.

Is there anything I need to do or avoid?

We ask that you avoid getting pregnant during the study. We also ask that you let us know if you start using hormone-based medications (e.g. the contraceptive pill or hormone coil) or antibiotics during the study. If you opt to provide tissue samples from the lining of the womb (endometrial biopsy), you may wish to take painkillers (e.g. what you would take for a headache) approximately 1 hour before the procedure. You do not need to abstain from sexual intercourse before or after the biopsy. This biopsy will not be performed if you have had unprotected sexual intercourse since your last period.

What are the possible benefits of taking part?

There will be no direct benefit of taking part, but the results from this study might help to improve the healthcare of patients in the future.

What are the possible disadvantages of taking part?

There is a small risk of discomfort and bruising associated with taking a routine blood sample. There is also a risk of mild lower abdominal pain or discomfort when obtaining a sample from the lining of the womb. This normally lasts for a few minutes. You may wish to take painkillers (e.g. what you would take for a headache) either before or after your procedure. Most people will also experience light bleeding following this procedure that can last a few days. A small risk of infection is associated with both the blood sample and sample from the lining of the womb. It is possible that participation will reveal unexpected findings which require further medical investigation, e.g. on ultrasound scan. You will be informed of these results and, with your consent, your GP will be informed and further medical review arranged.

What if there are any problems?

If you have any concerns or questions about any aspect of this study, please contact the clinical research team on 0131 242 1216 or 07435099926 who will do their best to answer your queries. If you wish to make a complaint at any stage during the study, you should ask to speak to the clinical researchers who will do their best to address your concerns. If you remain unhappy and wish to complain formally, you can do this through the NHS Lothian Complaints Procedure. Details can be obtained from the NHS Lothian Complaints Team at Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG. Telephone number 0131 536 3370, email feedback@nhslothian.scot.nhs.uk.

In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against NHS Lothian, but you may have to pay your own legal costs. The normal National Health Service complaints mechanisms (detailed above) will still be available to you.

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

If you wish to withdraw from the study, you can stop participation at any point, without giving a reason. In this case, we will assume that you are happy for us to use information/samples you have already supplied. You may choose to withdraw all data and samples from the research, by contacting the research team to inform us of this. Any samples which have been anonymised and analysed may be unable to be withdrawn, but we will stop using your data and samples in future analysis.

What happens when the study is finished?

For this study, the information and samples you provide will be used by researchers to investigate differences between women with heavy menstrual bleeding and normal menstrual bleeding. Your anonymised information and samples will be stored in the Centre for Reproductive Health at the Institute for Regeneration and Repair (University of Edinburgh). Anonymised information will kept for a minimum of 5 years from the end of the study. Personal data will be stored by the clinical research team for a maximum of one year following the end of the study. Personal data collected as part of this study will be retained for longer if you have agreed to be contacted about future research studies.

If all of the samples are not used for this study, we will ask for your consent to keep these anonymised samples to be used in other related approved studies. The samples are a valuable resource and could be used many times by researchers in several different studies using modern laboratory techniques. At present, future studies cannot be specified in detail, but may also involve collaboration with laboratories in other universities or commercial companies in the UK and overseas.

Future studies may include DNA analysis of samples, and you will have the option to opt out of this aspect of the research if you wish. DNA research includes the examination of your genes, where we can sometimes see patterns in people with similar medical conditions, for example heavy bleeding.

You also have the option to consent to researchers contacting you in the future about participation in future studies where your details would be revealed to researchers, you will not be contacted about future research using your anonymised samples or data.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

How will we use information about you?

We will need to use information from you and your medical records for this research project. This information will include; your name, Community Health Index (CHI) number (this is a unique numerical identifier which is used to identify healthcare patients in Scotland), contact details (email address, phone number and address) and health information. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. The anonymous data will be stored at The University of Edinburgh and may be considered for possible use in future ethically approved projects.

What are your choices about how your information is used?

If you wish to withdraw from the study, you can stop participation at any point, without giving a reason. In this case, we will assume that you are happy for us to use information/samples you have already supplied. You may choose to withdraw all data and samples from the research, by contacting the research team to inform us of this. Any samples which have been anonymised and analysed may be unable to be withdrawn, but we will stop using your data and samples in future analysis. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from [**www.hra.nhs.uk/patientdataandresearch**
- by asking one of the research team
- by contacting the Data Protection Officer's

What will happen to the results of the study?

The results of this study may be presented at scientific conferences and published e.g. in medical journals, reports and textbooks. You will not be identifiable from any published results. The results may be used to identify and manage heavy menstrual bleeding. You will be able to see the published results of the study on our website www.ed.ac.uk/hope.

Who is organising and funding the research?

This study has been organised by Dr Maybin. The University of Edinburgh and NHS Lothian are co-sponsors for the study, based in the United Kingdom. The study is being funded by Wellbeing of Women as part of a Research Fellowship for a PhD project.

Who has reviewed the study?

All the research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from West of Scotland Research Ethics Committee, which has responsibility for scrutinising all proposals for medical research of humans, has examined the study and has raised no objections from the point of view of research ethics. NHS Management Approval has also been given. The study has also been reviewed by a Patient and Public Information group and their suggestions incorporated into the study design.

Researcher Contact Details

If you have any further questions about the study, please contact the clinical research team on 0131 242 1216 or 07435099926 or via email; laura.le.edwards@nhslothian.scot.nhs.uk

Independent Contact Details

If you would like to discuss this study with someone independent of the research please contact Dr Kirsty Munro on 0131 536 1000 at the Royal Infirmary of Edinburgh.

Thank you for reading this information sheet