Study Of Novel eNdometrial cancEr diagnosTics - The SONNET study

Prospective observational study of novel diagnostic tools for suspected endometrial cancer

Participant Information Sheet (P.I.S) – Multicentre study

You are being invited to take part in a research study looking at improving care for people undergoing investigations for bleeding after the menopause. This research will form part of a PhD thesis. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if anything is unclear or if you would like more information. Thank you for taking the time to read this.

➢ What is the purpose of the research?

Bleeding after menopause can sometimes be a sign of womb cancer, and people with this symptom may be offered several invasive tests. These include an internal (vaginal) scan, a camera test inside the womb (hysteroscopy) and a biopsy of the lining of the womb (endometrium). Some women find hysteroscopy and biopsy uncomfortable or even painful, and often multiple trips to the hospital are required, which can be worrying. **However, only about 5 in 100 people who experience bleeding after the menopause are diagnosed with womb cancer**.

We are exploring new patient-friendly tools to **identify people who need these invasive tests to rule out womb cancer, and who can be safely reassured without them**. This will reduce the burden of invasive investigations on women who do not need them, and enable us to identify and diagnose women with cancer sooner. The SONNET study aims to find out how accurate these new tools are. To do this, we're recruiting around 3,000 people from gynaecology clinics across hospitals in England, Wales and Scotland.

➢ Am I suitable to take part?

You can take part if you are attending a clinic because of bleeding after the menopause. You cannot take part if you have been treated for womb cancer in the past, or have had a hysterectomy (womb removed).

➢ What would my involvement be?

The study visit would take place alongside your gynaecology clinic appointment. Taking part would mean that your appointment will be 30 minutes longer.

We will ask you to sign a consent form, take some details about your symptoms and your medical history, and then ask you to self-collect a urine sample (up to 50mls) in the bathroom. We would also like to take blood samples (up to 30mls) and a vaginal swab sample from you, but these are optional. We will ask you to complete a questionnaire about your health. This can all be completed on the same day.

You will then attend your clinic appointment as normal. After your clinic appointment, we will ask you to complete a questionnaire about how you found the tests. The questionnaire will be completed using an electronic tablet, or a paper form if you prefer. If you have further tests, we will phone you to ask some short questions about how you found each test. Alternatively, we may send you a link to complete the questions by text or email. With your permission, we will access your medical records to find out the results of any tests carried out, and your vaginal scan may be reviewed by an independent expert.

We would also like to ask **what you think** about the new tools we are developing – this part of the study is optional. If you are happy to be contacted to take part in an **interview, workshop or survey**, please indicate this on the consent form, and the study team at The University of Manchester will contact you separately.

➢ How is the vaginal sample collected?

Please avoid having a bath or swimming for 24 hours prior to your appointment, as this can wash away the cells we need to collect. A speculum will be used to gently open the vagina. The clinician will then insert a swab (similar to a long cotton bud), and rotate it gently for 10-30 seconds. If you prefer, we will collect the sample without using a speculum.

➢ What will happen to the samples I give?

Your samples may be used to test the accuracy of 3 different tests: a risk prediction tool called **PREDICT-EC** (which combines information about you with the results of your internal vaginal scan and urine test), a **spectroscopy** test (which uses a blood orurine sample) and the **WID®-easy** test (which uses a vaginal sample). Further biomarker discovery work may also be performed on your samples.

Testing and storage of urine, blood and vaginal samples will take place at Manchester University NHS Foundation Trust, Lancashire Teaching Hospitals NHS Foundation Trust or The University of Manchester laboratories. Some of the blood sample will be transferred to a commercial company called Dxcover (UK based) for further spectroscopy testing. Your vaginal sample will be transferred to a commercial company called AGHealth (UK based), where the WID®-easy test is performed. The samples will contain a random ID number, your initials and date of collection only.

We ask your permission to use any residual samples, including DNA from your blood sample, for future research, which may include genetic testing, in the UK or abroad. This may include commercial companies. The **people performing these tests will not know who you are, since your personal details will be removed**. **This part of the study is completely optional.** The samples will be stored at Manchester University NHS Foundation Trust Biobank or The University of Manchester. If you don't want your samples to be used in future research projects, we will dispose of them safely when no longer needed.

➢ Will I find out the results of the research tests?

We will not provide individual research test results, but we will provide a summary of the study findings on the study website https://www.bmh.manchester.ac.uk/research/projects/sonnet/

➢ Are there any risks?

Your clinic appointment will take around 30 minutes longer. You will receive usual NHS care for people experiencing bleeding after the menopause, and **your medical care will not be affected in any way**. You may feel a scratch and experience bruising if you provide a blood sample.

➢ Are there any benefits of taking part?

There is no direct benefit to you from taking part in this study. You will contribute to research that may, in the future, reduce the burden of unnecessary invasive tests on women with bleeding after the menopause.

➢ Where can I find more information?

On our study website https://www.bmh.manchester.ac.uk/research/projects/sonnet/
You can also watch a short video here

➢ Who will conduct the research?

Professor Emma Davidson, Dr Eleanor Jones and Dr Maya Whittaker, from the Division of Cancer Sciences at The University of Manchester are conducting this research. The spectroscopy analysis is led by Dr Gemma Owens at Lancashire Teaching Hospitals NHS Foundation Trust.

➢ Who has reviewed the research project?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by London Central Research Ethics Committee, REC ref 26/LO/0259 , IRAS project ID 361257.

➢ Who is funding the research project?

This National Institute for Health and Care Research, funder references NIHR304303. The doctors and nurses involved in the study will not receive any payments for including you in the study.

➢ Will the outcomes of the research be published?

Study results will be published in scientific journals, student dissertations and postgraduate thesis. They may also be publicised through social media and research websites, at international conferences and via charity, patient support group blogs, podcasts and tweets. You will never be identified in person in any report about the study or in the study results.

➢ Will I be compensated for taking part?

You will not receive money or reimbursement for taking part in this study.

➢ What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether or not to take part. If you would like to take part, please get in touch with the study team using the contact details at the end of this information sheet. If you do decide to take part you will be given this information sheet to keep, and will be asked to sign a consent form.

Data Protection and Confidentiality

➢ How will we use information about you?

We will need to use information from you and from your medical records for this research project. This information will include your:

- NHS number
- Name
- Laboratory results
- Age
- Contact details
- Demographics, ethnicity
- Medical history including past and future test results
- Record of consent

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.

The University of Manchester is the sponsor of this research. The University of Manchester is responsible for looking after your information.

We will share your information related to this research project with the following types of organisations:

- University Hospitals of Derby and Burton. They will review the coded ultrasound scans to ensure they have been interpreted consistently for research purposes.
- AGHealth (Advanced Global Health Ltd). They are a UK based commercial company who perform the WID®-easy test.
- Dxcover Limited. They are a UK based commercial company working on the Dxcover Gynaecology Liquid Biopsy test, with the aim of enabling earlier detection of gynaecological cancers
- Lancashire Teaching Hospitals NHS Foundation Trust. They will conduct spectroscopy analysis and will have joint responsibility for any data we share with them.
- Demographic data from the optional questionnaires (not linked to your name or another identifier) may be used for other educational and research purposes in the future.

International transfers

We may share or provide access to data about you outside the UK for research related purposes to:

- Developing a point of care spectroscopy device. This will be developed in future by Lancashire Teaching Hospitals and NSV Tech separately to this study, however data from this study will be used in its development.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Commercial technology companies: NSV.Tech. NSV.tech are based in the United States of America and aim to develop a point of care spectroscopy device.

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- The countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says.
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/report-a-breach

We will keep all information about you safe and secure by:

- **Your name and any other identifying information will be removed and replaced with an ID code (pseudonymised).**
- **We will only share pseudonymised data that is needed for developing the devices and tests. That means identifiable details like your name, address and NHS number will be removed.**
- **Only your hospital research team will have access to the key that links this code to your personal information.**
- If you consent to being contacted for future interviews or workshops, you preferred contact details will be transferred and stored securely by The University of Manchester and you will be contacted at a later date.
- Your consent form will be retained for 5 years in a locked cabinet on NHS premises for audit purposes.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 15 of years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop.
- you have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- 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, including the specific mechanism used by us when transferring your personal data out of the UK:

- our leaflet Privacy Notice for Research and **www.hra.nhs.uk/patientdataandresearch**
- by asking one of the research team
- by sending an email to dataprotection@manchester.ac.uk , or
- by ringing us on 0161 275 7789.

What if I have a complaint?

If you have a complaint that you wish to direct to members of the research team, please contact:

- Professor Emma Davidson (Chief Investigator); 0161 701 6492, or email emma.davidson@manchester.ac.uk

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information Tel 0303 123 1113

If you are unhappy with the care you have received, you can make a formal complaint by contacting the National Health Service Patient Advice and Liaison Service (PALS) https://www.nhs.uk/nhs-services/hospitals/what-is-pals-patient-advice-and-liaison-service/. In the unlikely event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester or NHS Trust but you may have to pay your legal costs.

Contact Details

If you have any queries about the study or if you are interested in taking part contact:

If you have been invited to take part in SONNET by the hospital at which your appointment takes place, please contact them directly. For general queries, please contact :

Name: SONNET Research Team
Email. sonnet@manchester.ac.uk