Pilot study to investigate the **A**ccuracy and potential clinical application of a non-invasive **D**iagnostic **D**evice, EVG Clinical Decision Tool (Endosure test, EndoSure Inc), in the diagnosis and management of **END**ometriosis.

(**ADDEND** Study)

Participant Information Sheet

1. You are invited to take part in our research study

Our hospital is undertaking some research to find out how accurate a new non-invasive test, called Endosure, is in detecting endometriosis.

This study is called the ADDEND study and this information sheet is to help you understand why the research is being carried out and what it will involve for you if you decide to take part.

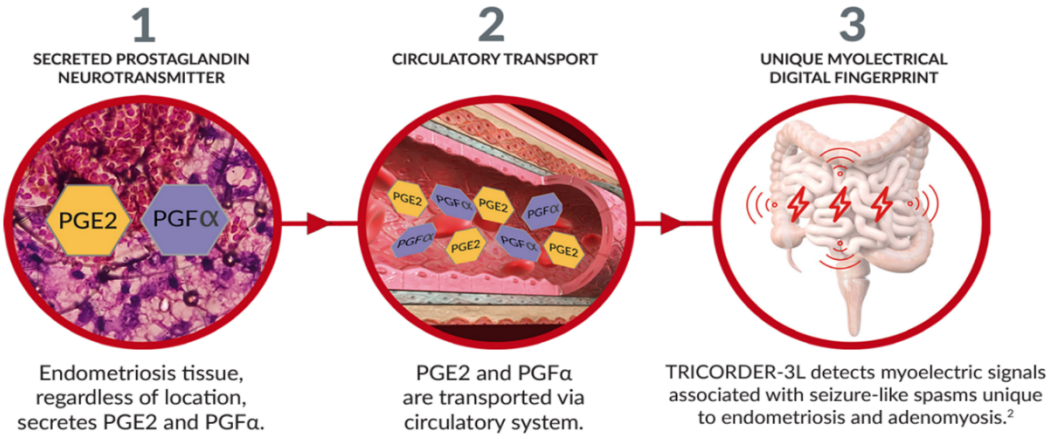
Please take time to read this information and ask us if there is anything that is not clear to you, or you would like more information. You may want to talk to others about the study before you decide to take part. It is entirely your decision whether to take part in this study. If you agree to take part, you are free to stop at any time without giving a reason. If you choose not to take part, this will not affect the care you receive from your doctors, and your care will continue in the usual way.

2. What is the purpose of this study?

Endometriosis is a disease that affects approximately 190 million women worldwide. Diagnosis of this disease faces a number of challenges. Current gold standard for diagnosis is laparoscopic surgery and biopsy. However, literature reports variable rates of diagnostic accuracy between 50 and 70%. There is an average wait of 8 years from the onset of symptoms to diagnosis. Imaging options available at present are Transvaginal ultrasound and MRI. Not all sonographers have expertise to look for signs of endometriosis on ultrasound. MRI is an expensive resource and there is a long wait for it. Also, GPs cannot request the MRI and it needs expertise to interpret and report images.

There is a need for a non-invasive, highly accurate, low-cost alternative for diagnosis. The advantages of such a diagnostic test would be earlier diagnosis, continued monitoring post therapy, as well as the ability to track the natural history of a disease that still remains a mystery, centuries after it was initially discovered.

According to recent evidence published in the literature two specific chemicals are released in endometriosis - PGE2 and PGF2α. These chemicals cause contractions of the small intestine thus producing a signal, which can be detected by a non-invasive test called Endosure.



3. Why have I been invited to take part?

We are inviting 78 women to join the study. The study has three groups: patients with pelvic pain and suspected endometriosis; patients who are having laparoscopic surgery for any other reason; and, healthy women with no complaint. You have been invited to help because you are likely to belong to one of these groups.

4. Do I have to take part?

It is up to you whether you take part in the study. We will talk to you about the study and answer any questions you may have. If you agree to take part, we will ask you to sign a consent form.

Taking part in the study does not affect your access to any other treatments.

If you choose not to take part in the study, your clinical care will continue as normal.

5. What would taking part involve?

If you agree to take part, you will have an extra clinic appointment at the Hospital. The test is an additional element to your standard care. The test is double-blinded; researchers and patients will not be notified of the test results until the end of the study. The results do not change the management in any way.

What happens during the test?

The procedure takes 30 mins, with 10-20 mins needed to prepare you for the test. It requires no special preparation or any anaesthesia.

Electrodes are placed on the skin on your abdomen (shaving at the specific electrode points may be required) and will remain in place for duration of the study.

Throughout the test you will be asked to remain in a reclining position. Loose fitting clothing should be worn and during the test, and your clothing may be adjusted lower down on your hips and /or

above your lower ribs. You must use bathroom prior to the start of the test as you cannot move once the test begins.

For the first 10-15 minutes a baseline recording of your gastrointestinal electrical signals is taken. A water load satiety test is performed. You will be asked to drink water during a five-minute period of time until you feel full. If this occurs in less than five minutes, then you may stop at that time.

The gastrointestinal electrical signals are then recorded over the next 30 minutes, after which the electrodes are then removed, and the test is over.

This is a double blinded study implying that the patients and the doctors are not aware of the test results during the study.

Preparation required for the test

7 days before the test – no opioid medications

3 days before the test – no nausea or anti-spasmodic medication

8 hours before the test – nothing by mouth except sips of water

2 hours before the test – nothing by mouth

Nothing should be eaten after midnight the day before the test. Small sips of water can be taken until two hours before the test.

Can I take my medications prior to the test?

Take critical medications such as those for your heart, blood pressure, asthma or seizures, with sips of water on the morning of the test.

Medications that can affect this test

Prokinetic medications such as metoclopramide, tegaserod, erythromycin, domperidone, bethanechol and antispasmodic medications such as dicyclomine, donnatal, hyocyamine or glycopyrrolate should be discontinued 3 days prior to the test.

Pain medications can also slow down the intestine and can affect this test. They include codeine, morphine, oxycontin, oxycodone. These medications should be stopped 7 days prior to the test. The list is not exhaustive, if in doubt check with the clinical staff when making the appointment.

GP Involvement

With your permission, we will write to your GP to inform them about your participation in this study.

6. What are the possible benefits of taking part?

There are no specific benefits to the participants. However, research does deliver wider benefits to society / others with a similar condition and some indirect benefits might be foreseeable for participants themselves.

7. What are the possible disadvantages and risks of taking part?

There are no risks associated with this test. There are no components that are used during the test equipment that are harmful. Please alert the technician or the person performing your test if you have any allergies to adhesives.

Is there any pain associated with this test?

There is no pain associated with this test. The test is completely non-invasive. There are no needles or need to obtain samples of your blood or tissues. There are no medications required nor anaesthesia or sedation.

8. What if there is a problem?

If you have concerns or questions about any aspect of this study, you should speak to members of the endometriosis team at Worcestershire Acute Hospitals NHS Trust.

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure via the Trust Patient Advisory and Liaison Service (PALS).

Contact details are provided at the end of this information sheet.

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

You are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw, we will no longer collect any information about you, but the information already collected will not be erased and this information may still be used in the project analysis.

10. How will information about me be used?

Researchers at Worcestershire Acute Hospitals NHS Trust will need to use information from you, and your medical records for this research project. This information will be kept strictly confidential, and stored on a password protected hard-drive at the Trust. The researchers will only be given as much information from your medical records as is needed for this research and that information will be anonymised.

People who do not need to know who you are will not be given your name, where you live or anything that could identify you, your information will have a code number instead. All information about you will be kept safe and secure.

The results of the test will be conveyed to you and your GP at the end of this study.

Once the study has finished, the data will be kept for a minimum of 10 years. Reports will be written in a way so that no-one can work out that you took part in the study.

In accordance with Sponsor, Government and funder policies, we may share anonymised research data with researchers in other organisation, including those in other countries. Sharing research data is important to understand the bigger picture in particular areas of research.

11. 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.

We need to manage your records in specific ways for the research to be reliable. Under UK Data Protection laws the Trust is the Data Controller (legally responsible for the data security), and the Chief Investigator of this study is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally-identifiable information possible.

After 10 years your data collected during the study will be disposed of securely.

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

You can find out more about how we use your information:

- At https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/
- By asking a member of the research team

13. Who is organising and funding this study? How has it been approved?

The study is being organised by Worcestershire Acute Hospitals NHS Trust (the Sponsor). The funding for the trial is provided by the British Society of Gynaecological Endoscopy (BSGE) (Research Grant/Ref 36). Miss Donna Ghosh, Consultant in Gynaecology, and Trust Endometriosis Lead is the Chief Investigator of this study. 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 favourable opinion by REC TBC.

The Trust patient-focussed Endometriosis Group have helped us plan and design this study, and to create the patient documentation.

14. What happens at the end of the study?

When your Endosure test has been completed, your treatment will continue as usual. If you withdraw from the study, we will need to keep and use the data collected up to your withdrawal. At the end of the study the results will be published in scientific medical journals and presented at conferences. You will not be identified in any publication.

15. How to contact us

Contact details of your local care team:

Joanna Street

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01905761489

Worcestershire Acute Hospitals NHS Trust Patient Advice and Liaison Service
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wah-tr.PALS@nhs.net