Deep endometriosis: management by medical treatment versus early surgery: DIAMOND

PARTICIPANT INFORMATION LEAFLET

DIAMOND website address:
https://w3.abdn.ac.uk/hsru/DIAMOND

INVITATION TO TAKE PART
We would like to invite you to take part in DIAMOND, a research study looking at treatments to manage pelvic pain caused by deep endometriosis. The study is funded by the National Institute of Health Research (NIHR, the research arm of the NHS).

Before you decide if you would like to take part, it is important for you to understand why the research is being done and what it will involve.

The first part of the Participant Information Leaflet tells you the purpose of the study and what will happen to you if you take part.

Then, in the second part we will give you more detailed information about how the study is run.

Please take time to read the information carefully, which has been written with the help of patient representatives with endometriosis. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

BACKGROUND TO THE CONDITION

Endometriosis is a common condition affecting 1 in 10 women, which can cause severe pain. It happens when cells similar to those lining the womb grow outside the womb, generally on surfaces and organs within the pelvis, causing bleeding, scarring and inflammation. Occasionally, rather than growing on or very near the surface, the endometriosis cells can grow deeper into tissues and organs, such as the bowel, bladder and the vagina causing a painful condition called deep endometriosis.

Deep endometriosis is treated in one of two ways:
• by taking hormones which can shrink areas of existing endometriosis and prevent new areas forming by stopping the growth of abnormal cells
• by using keyhole (laparoscopic) surgery to remove areas of endometriosis

The limited research that has been done in this area suggests that, for women with deep endometriosis, hormonal treatment over many months could be just as effective as surgery in relieving pain. Clinical guidelines used in the NHS state that either hormones or surgical treatment can be used to treat deep endometriosis. The guidelines do not recommend one treatment over the other because there is a lack of evidence from research to tell us which is the best treatment for women with deep endometriosis.

The DIAMOND study will compare the benefits and risks of medical (hormonal) management versus surgical treatment for deep endometriosis. We will monitor your symptoms for up to 18 months.

WHAT IS THE PURPOSE OF THE RESEARCH STUDY?

This clinical research study will help gynaecologists, GPs, patients and health services decision-makers understand what the most effective treatment is for women who have pelvic pain caused by deep endometriosis.

At the moment, there are two treatment options available for women with deep endometriosis. However, it is unclear which treatment is the best to offer to patients. The way we find this out is to conduct what is called a randomised controlled trial, also called a RCT.

In this study, we want to compare medical (hormonal) management with surgery to see which is better for treating your symptoms.

The medical (hormonal) treatments used in the study are all commonly used in the NHS for women with endometriosis, including deep endometriosis. Some of them are also used as contraceptives such as the combined pill and progestogen hormone tablets and implants. You will not be prescribed a medication which you have previously used that didn't help your symptoms. Surgery is usually by laparoscopic (keyhole) surgery under general anaesthetic (asleep) where the endometriosis is removed by surgeons in specialist endometriosis centres.

The study will run for four years and aims to recruit around 400 participants with deep endometriosis who are not actively trying for a pregnancy, from hospitals across the UK.

WHAT WOULD TAKING PART INVOLVE?

If you decide to take part in this research study, you will be randomly allocated (using a computer) to one of the two study groups mentioned above. Being randomised means that neither you nor your doctor/healthcare team will decide which treatment you receive.

Either

- You will be in the group where medical (hormonal) treatment is used to treat your endometriosis

Or

- You will be in the group where surgery is used to remove endometriosis.

There is an equal chance that you will be placed into either treatment group. This helps make sure that the research study compares groups of similar individuals where the only difference is the treatment given.

If you decide to take part, you should keep a copy of this leaflet and we will ask you to complete a consent form confirming that you are happy to take part. We will then ask you to complete a questionnaire (which should take less than 20 minutes to complete) about your pain, quality of life and symptoms.

We will ask you to complete additional questionnaires (at 3, 12 and 18 months after you join the study) about your pain, quality of life, symptoms, and any treatments you have had for deep endometriosis. All of these questionnaires will take less than 20 minutes to complete. These will be sent by the study office in Aberdeen either by post (and returned to Aberdeen in the pre-paid envelope provided) or by email or text message (depending on your preference) with a link to complete the questionnaires online. We may send you reminders about completing the questionnaires to make sure relevant information about you is recorded for the study.

We will also ask a small number of women to take part in telephone or in-person interviews to find out how they make decisions about taking part (or not) in the DIAMOND study and how their symptoms change over time. We will ask you whether you would like to know more about these interviews and give you another information leaflet to read if you are interested.

If you are in the study group randomised to medical (hormonal) treatment, you and your clinical team will decide the best medical treatment for you. We will write to your GP and ask them to prescribe the treatment which has been agreed, for 18 months. You should continue to use some form of contraception throughout the study.

You may switch forms of medical treatment, depending on your preference and how well you tolerate the medical treatment. However, hormonal treatment should continue for 18 months unless:

• You feel unable to continue with that medication. If this does happen, we will stop the medication and find an alternative for you.

•You become pregnant. If this happens, we would like to keep you in the study to find out how you are but advise you not to take further hormonal treatment until your pregnancy is complete.

If you are in the group allocated to receive surgery, you will be added to the waiting list for the surgery. You should continue using your usual contraception throughout the study.

You will be admitted to hospital for the day or overnight. You will be given a general anaesthetic. Small cuts are made on your abdomen so instruments can be inserted to

visualise the organs and to remove areas of endometriosis. Recovery time varies but should be between 2 and 6 weeks.

You can still take hormonal treatment after surgery as recommended by your doctor, to reduce the chance of your endometriosis coming back, or as a contraceptive. This will be a decision made between you and your doctor.

Whichever group you are allocated to, you can also be given additional pain relief medication, if needed. You can also take over the counter medication if needed.

With your permission, we will also collect relevant data (e.g. further treatment, pregnancy) at 18 months from the hospital, GP or by linking to patient prescribing data (e.g. NHS Digital Data Access Request Service or equivalent) to accurately record medications you have been prescribed during your follow-up in the study.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

You may not benefit personally from taking part. The results of this study will help women like you with pain and endometriosis and will help health services to provide effective care in the future for women with deep endometriosis. If you are having problems or are unhappy with your management during the study, you will be able to contact the local research nurse to discuss alternative treatment.

WHAT ARE POSSIBLE DISADVANTAGES, RISKS AND SIDE EFFECTS WHEN TAKING PART?

We do not think that there are any possible disadvantages to you. All procedures and techniques are already being used in the NHS to treat patients with deep endometriosis.

If you take part in DIAMOND, there should be no **additional** risk to you. Whichever treatment group you are allocated to, your care will be undertaken by a competent and trained doctor. There are risks associated with all procedures, anaesthetics and medications. Steps are always taken to ensure that these risks are minimised, whether in routine hospital care or clinical research. As part of routine care, you will be informed of potential risks of surgery and side effects of medication.

DO I HAVE TO TAKE PART?

No. It is entirely up to you whether or not you take part. Please take as much time you need to make this decision. You can read this information leaflet as many times as you wish and ask your doctor and/or research nurse as many questions as you like.

You can decide at any time to withdraw from the study. This decision will not affect the standard of care you are receiving now or in the future. If you make this decision, you should continue attending appointments with your consultant and/or GP as part of your routine care.

If you decide to withdraw from this research study, we will keep and use all the data we have previously collected about you. We will not collect any further data about you. This information will remain confidential and will not be used for any other purpose. To safeguard your rights, we will use the minimum personally identifiable information possible.

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

If the study is stopped earlier than expected for any reason, we will tell you and arrange continuing care for you.

WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the DIAMOND Study Office staff will contact you to let you know about the choices available to you. However, we are not aware that any new, relevant information is likely to become available before the end of this study.

WHAT IF THERE IS A PROBLEM?

If you have a question or concern about the study, you can ask to speak with the research team who will do their best to answer your questions. Contact details for your local study nurse and the Study Office can be found on the last page of this information sheet. If you wish to complain formally or have any concerns about any aspects of the way you have been approached or treated during this study, you can do this through the normal NHS Complaints Procedure. Details can be obtained from your hospital.

We do not expect any harm to come to you by taking part in this study. In the event that something does go wrong, and you believe that you are harmed by taking part in this study, you have the right to pursue a complaint and seek compensation through the research sponsors of this study, the University of Aberdeen and NHS Grampian, researchgovernance@abdn.ac.uk.

If you are harmed due to someone's negligence, then as a patient of the NHS, you may have grounds for legal action. You may have to pay for your legal costs yourself.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

Yes. We will follow ethical and legal practice and all information which is collected about you for the purpose of this research study (Name, Date of Birth, Address, Contact details and Hospital number/CHI number (Scotland only) will be handled in strict confidence and securely stored by the University of Aberdeen.

WHO WILL HAVE ACCESS TO MY INFORMATION IF I TAKE PART IN THE STUDY?

The local research team at the hospital that you were recruited in will have access to your information. They will use your name and contact details to contact you about the study, to make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

The study team, who are based in the Centre for Healthcare Randomised Trials (CHaRT) at the University of Aberdeen, will have access to your information to contact you about the study, for example to send you the questionnaires, and for quality control purposes, such as auditing the data collection process. All electronic data collected for the purpose of the research study will be confidentially and securely stored on computer servers maintained by the University of Aberdeen. The local research team will pass information collected from you and your medical records to the study team.

We will tell your GP you are taking part. If you are in the medical (hormonal) treatment group, we will ask the GP to give you a prescription for the treatment recommended by the hospital team.
We also plan to seek funding to follow up participants in the longer term using data from NHS and other government central registries, and GP and hospital notes. NHS central registers: in England this is NHS Digital, in Scotland this is the Information Services Division [ISD], and in Wales this is the NHS Wales Informatics Service [NWIS]. The reason for this is to make sure that we have the correct information about all the participants taking part in this study and ensure that the results are as accurate as possible. In order to do this, we would need to securely send the NHS central registers some information about you (e.g. date of birth, name, and address). They will then match this information to their records and using your study number securely send any hospital readmission data back to the Trial Office.

The statistical, health economics and qualitative analyses of the study are being conducted at the University of Aberdeen. To maintain confidentiality, these team(s) will only analyse anonymous data. (Anonymous data does not include names or addresses, and it is not possible to identify individual participants from anonymous data).

Other individuals from the University of Aberdeen, NHS Grampian, the Research and Development Department of your local NHS Organisation may look at your medical records and data collected for the study, to check that the study is being carried out correctly and to check the accuracy of the research study. All will have a duty of confidentiality to you as a research participant.

Other researchers may wish to access anonymous data from this study for future research. If this is the case, they would be expected to follow legal, data protection and ethical guidelines. It will not be possible to identify you from this data. The information will only be used for the purpose of health and care research and cannot be used to contact you or affect your care.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

HOW LONG WILL MY INFORMATION BE KEPT?

All information which is collected about you during the research, including identifiable data, will be held securely for 10 years after the trial has finished in accordance with Sponsor requirements and data legislation.

WHO IS RESPONSIBLE FOR MY INFORMATION?

The University of Aberdeen is the data controller for this study and is responsible for looking after your information, using it properly and complying with your rights. You can find more about this at www.abdn.ac.uk/privacy or by contacting us at the address below.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of the study will be used to make recommendations on treatments for patients with deep endometriosis. We will publish the results of this study in scientific journals and present the information at appropriate meetings. You will not be identified in any publication of results of the study. We will let you know the results of the study when it is finished unless you tell us that you do not wish to know.

WHO IS ORGANISING AND FUNDING THE STUDY?

This study is sponsored by the University of Aberdeen and NHS Grampian who have overall responsibility for the management of the study. The study is funded by the National Institute of Health Research (NIHR, the research arm of the NHS). The research is being carried out by a group of experienced healthcare professionals and researchers from the Centre for Healthcare Randomised Trials (CHaRT), a UKCRC registered Clinical Trials Unit at the University of Aberdeen in collaboration with Birmingham Women's NHS Foundation Trust, Royal Cornwall Hospitals NHS Trust, University of Nottingham, University of Birmingham, University of Bristol, University College London, University of Edinburgh and Endometriosis UK.

WHO HAS REVIEWED THE STUDY?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed and given favourable opinion by the West of Scotland Research Ethics Committee 4.

Thank you for reading this

Thank you for taking the time to read this information leaflet. We hope that it has been helpful in enabling you to decide if you would like to participate in the DIAMOND study. Please ask us if you have questions or would like more information about the study.

FURTHER INFORMATION AND CONTACT DETAILS

If you have any questions or would like any more information, please contact:

DIAMOND Study Office **Centre for Healthcare Randomised Trials (CHaRT),** **Health Services Research Unit** **University of Aberdeen** **Health Sciences Building** **Foresterhill** **Aberdeen AB25 2ZD** **Tel: 01224 <<43number>>** **Fax: 01224 438165** **Email: diamond@abdn.ac.uk** **Web: XXX**	**<<Local centre contact details>>**
We are working in association with Endometriosis UK. You can also find more information here. **Web: www.endometriosis-UK.org** **Tel: xxxx**	