University Hospitals of North Midlands NHS Trust
Research and Innovation
First Floor, B Block
Royal Stoke University Hospital
Newcastle Road
Stoke-on-Trent
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Participant Information Sheet (PIS)

Study title

Ureteric identification using IndoCyanine Green ('ICG') dye versus Conventional ureteric stenting to reduce post-operative pain and surgical morbidity during Endometriosis surgery: A pilot trial (ICE trial)

Invitation and summary

You are being invited to consider taking part in our research study. Before you decide whether to take part, it is important for you to understand why this research is being done and what it will involve. Please take time to read this information carefully and discuss it with friends and relatives if you wish. Ask us if there is anything that is unclear or if you would like more information.

Endometriosis is a common, non-cancerous condition where tissue like the womb lining is found growing elsewhere. Symptoms vary but can include intense pelvic pain and infertility. Endometriosis can be 'superficial' (sitting on the surface of organs in the pelvis) or 'deep', where it is found going inside these organs.

Endometriosis that is deep and painful may need surgery, which risks damage to the tubes that drain urine from the kidneys to the bladder (ureters). To reduce this risk, surgeons currently put tiny plastic tubes called "stents" inside the ureters so they can be seen more easily. These stents can stay for up-to 4-6 weeks following surgery but may cause pain and presence of blood in the urine. This is the current standard of care for this type of surgery.

Injecting a special dye into the ureters so they can be seen better, rather than using stents, might cause less pain for women after surgery, without making the operation last longer, or making complications (such as bleeding or damage to internal organs) more likely.

Before we can plan and run a full large clinical study, we need to understand whether this is possible and how best to do it, by doing a feasibility study.

Aims of the research

The overall aim of this study is to see whether there is a better outcome following surgery for deep endometriosis when using a dye, instead of plastic tubes, to identify the tubes ('ureters') linking the kidneys to the bladder. This research will also allow us to see if it is possible to run a larger scale trial.

Why have I been invited to take part?

You have been invited to participate because you will be undergoing surgery for deep endometriosis. We hope to recruit 70 patients from two sites.

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What will happen if I take part?

If you decide to participate, we will confirm that you are scheduled for endometriosis surgery and that you fit the inclusion criteria for the study. You will have the opportunity to discuss the study with the research team, ask questions, and give written informed consent. During surgery, you will be randomly assigned to one of two groups to have either the traditional technique (stents) or the new technique (dye). We will ask you about your pain levels, and how it affects your life, before and after your operation.

Group 1 (traditional technique stents): A small stent (soft tube) will be temporarily placed in each ureter to identify and protect it during surgery. The stents are either removed at the end of the operation or may be left in for4-6 weeks.

Group 2 (new technique dye): The dye will be injected through a ureteric catheter into each ureter. This dye allows surgeons to see the ureters under a special light. The dye is already approved for use as an intravenous diagnostic.

Both methods can be performed alongside your surgery for endometriosis without prolonging your procedure significantly. Patients undergoing ureteric stents will need to have a short ‘key-hole’ procedure to remove the stents that does not need general anaesthetic.

After surgery, your care and recovery will proceed as usual. You may be asked to attend additional follow-up visits or answer questionnaires about your experience, including any discomfort or complications. Both methods are widely used in medical practice and have a low risk of complications. Any risks will be fully explained before surgery. Participation is unlikely to affect your recovery timeline or standard care.

Endometriosis can be managed either with surgery or with medical treatment which includes medication for pain control and hormonal treatment (such as contraceptive pills or devices). If you and your doctor feel that surgery is a good option for you, you may be approached to take part in the study.

The surgery will be performed by a multidisciplinary team of gynaecologists, urologists and colorectal surgeons. If you take part in the study, you will have routine clinical follow up with your endometriosis team but in addition they will ask you to complete questionnaires at 6 and 12 weeks asking about how your operation has affected your pain, quality of life and if you have suffered any complications. We hope you will agree to take part in this trial and attend all follow up appointments.

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Participants will be given the opportunity to form a patient focus group and attend a meeting following the end of the study period to learn about their experiences of participation and the acceptability of study processes. This will help us to design a larger trial. There will be a maximum of 6 participants in the focus group.

Do I have to take part?

You are free to take part in the study or not. Your decision will not affect your clinical care. If you decide to take part, you will be asked to complete the consent form. You are free to withdraw yourself from the data collection process at any time. If you do wish to withdraw from the study you can do so, without affecting your rights to any future treatment or assessment you wish to have. If you wish to withdraw from the study, please contact a member of the research team using the numbers at the end of this information sheet.

What are the possible benefits of taking part?

Although there are no direct benefits to individuals, your participation will help guide the design of a full, large muti-centre trial to assess any additional benefits of using the proposed new dye technique during surgery for deep endometriosis over the current approach of using ureteric stents.

What are the possible risks or disadvantages of being in the study?

The techniques used in both methods are widely used in medical practice and have a low risk of complications.

All surgical procedures have some element of risk associated with them. However, as you have already been referred for surgery to treat deep endometriosis and will be undergoing the procedure in the near future, taking part in this study is not associated with any additional risk.

Insertion of stents or injecting dye into the ureters increases the chance of urinary tract infection, and stents on rare occasions may cause damage to the ureters causing bleeding.

Like all medicines, IndoCyanine Green (‘ICG’) dye can cause side effects, although not everybody gets them.

Together with the symptoms of the allergic reaction, an increase of special white blood cells associated with allergic reactions can occur (hypereosinophilia).

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The possibility of an allergic reaction is greater in patients with extremely serious kidney failure.

Who will have access to information about me?

Any data collected as part of this study will be accessible to the research team only. Your data will not be shared outside of the UK.

How will information about me be used?

We will need to use information from you and your medical records for this research project. This information will include your initials, NHS number, name and contact details. 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. University Hospitals of North Midlands NHS Trust (UHNM) is the sponsor of this research and is responsible for looking after your information. We will keep all information about you safe and secure

What are my choices about how my 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. Data collected during the study will be kept for at least 20 years in line with NHS England retention guidelines. 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 I find out more information about how my information is used?

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

- www.hra.nhs.uk/information-about-patients/
- By asking one of the study team (contact details at the end of this leaflet)
  By speaking to the Data Protection Officer – DPO.UHNM@uhnm.nhs.uk or 01782 676474

Will my taking part in this study be kept confidential?

Yes. All the information required for this study will be kept strictly confidential. All data will be kept securely. Each participant will be assigned a number, kept separate from her details (depersonalised data). As part of the consent process, we will ask your permission to allow

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authorised staff from UHNM and relevant regulatory authorities to access your medical records and data. This is to check that the study is being carried out correctly. The data collected as part of this study will be stored on a password protected computer database and/or in locked filing cabinets and will not be accessed by anyone outside of the study team and study organisers.

Will my GP be informed?

Yes, with your permission, your GP will be informed of your involvement in the study. This ensures that your GP notes are kept up to date and, if you need to see your GP, they will be aware of exactly what he the procedure is that you have had.

Will I receive any payments or expenses for taking part in the study?

You will receive no payments or expenses for this study. However, you will be pushing forward the knowledge boundaries of this procedure which many patients may benefit from in the future.

What if new information becomes available?

The study team will discuss any important new finding that may develop during the study. If you wish to opt out of the study, you can do so at any point, and your normal care will not be affected. If you wish to continue the study and new information becomes available, we may ask you to sign another consent form.

When will the study end?

Your participation ends after your postoperative follow-up. Standard surgical and medical care will continue as needed. The results of the study will help guide future care but will not directly affect your ongoing treatment.

Will my information be kept confidential?

Your information will be kept confidential and secure. Your name and hospital number will be securely stored next to a unique identifier. This unique identifier will be used throughout the analysis to ensure you remain anonymous.

Responsible members of the University Hospitals of North Midlands NHS Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will the use of my data meet GDPR rules?

GDPR stands for the General Data Protection Regulation. In the UK we follow the GDPR rules and have a law called the Data Protection Act. All research using patient data must follow UK laws and rules.

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Universities, NHS organisations and companies may use patient data to do research to make health and care better.

When companies do research to develop new treatments, they need to be able to prove that they need to use patient data for the research, and that they need to do the research to develop new treatments. In legal terms this means that they have a 'legitimate interest' in using patient data.

Universities and the NHS are funded from taxes and they are expected to do research as part of their job. They still need to be able to prove that they need to use patient data for the research. In legal terms this means that they use patient data as part of 'a task in the public interest'.

If they could do the research without using patient data they would not be allowed to get your data.

Researchers must show that their research takes account of the views of patients and ordinary members of the public. They must also show how they protect the privacy of the people who take part. An NHS research ethics committee checks this before the research starts.

What if there is a problem?

Complaints

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions on <insert local details>. If you remain unhappy and wish to complain formally, you can do this by contacting the hospital's advice and Liaison Service (PALS) or the Complaints Team.

Advice and Liaison Service (PALS) or the Complaints Team:

Telephone: 01782 676450/01782 676455

Email: patientadvice.uhnm@nhs.net

Address: Patient Advice and Liaison Service, Main Building, Royal Stoke University Hospital, Newcastle Road, Stoke-on-Trent, ST4 6QG

More information can be found at: https://www.uhnm.nhs.uk/our-services/patient-experience-and-pals

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Harm

The NHS indemnity operates in respect of the clinical treatment with which you are provided. In the unlikely event of harm during this research study due to someone's negligence, then you may have grounds for legal action for compensation against the Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What will happen to the results of this study?

At the end of the study, we will publish the findings. You will not be identifiable in any reports or publications resulting from this study. If you wish to receive information on the study findings, we can send this to you in writing.

Who is organising and funding this study?

The study is being funding by the National Institute for Health Research (NIHR) as part of the Research for Patient Benefit (RfPB) programme.

Who has reviewed 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 North West Greater Manchester West Research Ethics Committee.

Thank you for taking the time to read this Participant Information Sheet

Can I keep a copy of this information sheet?

Yes, please feel free to keep this document. If you decide to take part in the study, then you will be asked to sign a consent form and you will also be given a copy of that to keep.

Further information and contact details

CI/PI: Mr Gourab Misra, Consultant Gynaecologist on 01782 672361

RESEARCH TEAM: Louise Campbell, Senior Research Practitioner on 01782 672725