Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Local Trust Logo

Participant Information Sheet

The ORION Trial: RadiO fRequency ablatION for haemorrhoids

We would like to invite you to take part in a research study. Before you decide if you would like to take part, you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to family, friends, or health professionals about the study if you wish. Please ask 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.

Who to contact?

If you have any questions about the study, please contact:
INSERT LOCAL CONTACT DETAILS

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What is the purpose of this study?

Haemorrhoids are swellings around the back passage which can cause bleeding, pain and itching and can protrude. When they become enlarged, surgery is often advised as it is an effective way to control the symptoms. In this study, we are comparing a haemorrhoid treatment called radiofrequency ablation (RFA) with other haemorrhoid surgeries. Not enough research has been done on RFA yet to see if it is better than other surgical treatments. Therefore, this study aims to compare RFA with other surgical procedures for haemorrhoids.

What is Radiofrequency Ablation?

This is a treatment that uses radio waves to destroy the haemorrhoid. According to the research that has already been done, Radiofrequency Ablation is safe and there is only a little amount of pain. People seem to get over the surgery quickly and it may be as good as other operations to cure haemorrhoids. However, the new surgery has not been tested enough for us to be sure that it is as good in comparison to other treatments. By comparing Radiofrequency Ablation with other treatments, this will help the NHS decide if they should be spending money on Radiofrequency Ablation.

Why have I been invited to take part in this study?

You have been invited as you are undergoing surgical treatment for haemorrhoids.

Do I have to take part?

No, you do not have to take part; it is up to you to decide. We will describe the study throughout this information sheet, which you can keep. You do not have to decide today, the research nurse will call you before your next appointment and we will ask you for a decision at your next clinic appointment. If you do agree to take part, you are free to withdraw at any time, without giving a reason. Your decision to take part will not affect the standard of care you receive.

What will happen if I agree to take part?

Before you decide to take part, a member of the research team may ask you some questions to confirm your suitability for the trial and answer any questions you may have.

Consent: If you decide to take part, you will be asked to sign a consent form. This form confirms you are happy to take part and gives permission for your data to be used as part of the ORION trial. You will sign the consent form either face-to-face at your clinic visit or via the post. If consent is taken via the post, you will be sent two copies of the consent form to complete. You will need to complete both forms; you will keep one for yourself and return the other to the research nurse at your hospital. When they have received the consent form, they will contact you to check the form and complete some questionnaires with you.

The research nurse will then ask you some questions about your symptoms and quality of life. This will be either at your clinic visit or over the phone.

Randomisation: You will then be randomly allocated, by a computer, into one of two groups:

Group A: will receive radiofrequency ablation (RFA) or
Group B: will receive another surgery, determined by your surgeon. This will be one of the following treatments that are part of the usual treatment for haemorrhoids: Stapled haemorrhoidopexy, Haemorrhoidal Artery Ligation (HAL) or Haemorrhoidectomy.

The randomisation system is provided by the University of Sheffield. As we do not know which treatment is best, you have an equal (50/50) chance of being in either group. Neither you nor your doctor will be able to decide which treatment you will receive. You will not be told which operation you received, even after the trial has finished due to the possibility of a long-term follow-up.

Receiving the treatment: You will not be told which treatment you have received. However, your surgical team and some members of the research team will know this and all the details of the operation will be included in the notes and available to other doctors who are looking after you. This is called 'blinding' and is to ensure the data we collect is fair between the two groups. All of the treatments (Group A and Group B) are performed under general anaesthetic and receive the same aftercare. In some cases, local anaesthetic may be used, this will be discussed with you by your surgeon. This information will be discussed with you by your surgical team prior to the surgery. After the treatment, you will receive the same standard of care from your surgical team regardless of which treatment you received.

After the treatment: We would like to collect information from patients who take part for one year following treatment. In research, this is called 'follow-up' and is important so that we know about long term benefits or negative effects of any treatment. Follow-up will involve you answering questions about your general health, haemorrhoidal symptoms, including pain and incontinence and any further treatment you have had since the treatment. Follow-ups will be conducted by a member of the research team. In some instances, with your permission, follow-ups may also be conducted by a member of the central study team based at the Clinical Trials Research Unit at the University of Sheffield. We will contact you at the following times:

1) **1 day after surgery,** you will be contacted via a telephone call or the post to complete a short questionnaire about your pain and quality of life.
2) **7 days after surgery,** you will be contacted via a telephone call or the post to complete a short questionnaire about your pain and quality of life.
3) **3 weeks after surgery,** you will be contacted via a telephone call or the post to complete a short questionnaire about your pain and quality of life.
4) **6 weeks after surgery** you will attend a clinic appointment with the doctor where they will review your treatment; this would be the normal procedure following both treatments whether you take part in the research or not. You will be asked questions about your general health, your symptoms relating to haemorrhoids, such as pain, days lost of work and incontinence and any complications you may have experienced.
5) **1 year after surgery,** you will be contacted via a telephone call or the post to answer some of the same questions that you will be asked at your 6-week clinic visit. These

will be about your quality of life, pain, incontinence, complications and whether your haemorrhoids have returned.

One year after your treatment, the research nurse will also look at your hospital notes to see if you have been back to the hospital for treatment of your haemorrhoids. They will ask your consultant if you have been back for treatment and they will write to your GP to see if you have been to see them about your haemorrhoids. This is so we can see if you have needed any further treatment for haemorrhoids since taking part in the research.

What are the alternatives for treatment?

There may be other options for the treatment of your haemorrhoids and these can be discussed with your doctor before deciding whether to take part in the research**.**

What are the possible disadvantages and risks of taking part?

All treatments offered in the study are routinely offered in the NHS; both would be options offered to you if you did not take part in the trial and are considered to be safe treatments. However, RFA is not available in all NHS Trusts.

You will be asked to give up some of your time to answer the follow-up questions. However, these will be over the phone to minimise disruption to you. You may be asked some sensitive questions about your symptoms.

What are the side effects of any treatment received when taking part?

There are several possible side effects and some rarer outcomes associated the treatments and the anaesthetic required. Most of these side effects can occur with any of the procedures. They include;

Common (affecting less than 1 in 10 patients) outcomes following these operations include pain, bleeding, anal fissure and pain on defaecation.
Uncommon (affecting less than 1 in 100 patients) outcomes following these operations are postoperative haemorrhage (which may on rare occasions include the need for a blood transfusion), bleeding requiring re-admission to hospital and recurrence of haemorrhoids.
Rare (occur in less than 1 in 1,000 people) complications could include urinary retention, pelvic sepsis, pelvic abscess, anal stenosis, faecal incontinence, and systemic complications.

Side effects and complications of anaesthetic:
Common (affecting less than 1 in 10 patients) side effects from anaesthetic include:
Feeling sick and vomiting, sore throat, dizziness, blurred vision, headaches, bladder problems, minor damage to lips or tongue, itching, aches and pains, pain during injection for drugs, bruising and soreness, confusion and memory loss.
Uncommon (affecting less than 1 in 100 patients) side effects from anaesthetic include:

Chest infection, muscle pains, slow breathing, damage to teeth, an existing medical condition getting worse.
Rare or very rare (affecting less than 1 in 1,000 or 1 in 10,000 people) complications are: Damage to the eyes, heart attack or stroke, serious allergy to drugs, nerve damage, equipment failure. Deaths caused by anaesthesia are very rare. There are probably about five deaths for every million anaesthetics in the UK.

What are the possible benefits of taking part?

There are no guaranteed benefits to participating in this research. You will receive the appropriate health care by your consultant whether you choose to participate in the study or not. We do not know which type of surgery will be better for you in the long term. This is the reason for doing this research. By taking part in this study, you will be directly helping us to inform the treatment of future patients diagnosed with haemorrhoids that need surgical treatment.

What happens when the research study stops?

Your colorectal surgeon will continue your care and treatment.

What will happen if I do not want to carry on with the study?

You can withdraw from the study at any time without giving any reason, but you will still need to attend clinical appointments so that you can have your haemorrhoids monitored as part of your usual care. We will keep your data up until the point that you withdraw, and we will not collect any new information from you.

What if new information becomes available?

Sometimes during the course of a research study, new information becomes available about the intervention that is being studied. If this happens, the research nurse will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, the researcher will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

In some circumstances, on receiving new information the researcher might consider it to be in your best interests to withdraw you from the study. The researcher will explain the reasons.

Will my data be kept confidential?

If you decide to take part, you will be given an identification number for the study, and all information collected about you for the study will be linked to that number. That means only the people treating you, or who need to contact you, will have access to your personal information. Your GP will also be told that you are taking part. The outcomes of this research may be published externally in a journal, on a website or via a conference presentations; however you will not be identifiable from the published results. Your personal details will be kept strictly confidential.

Use of my data

Sheffield Teaching Hospitals NHS Foundation Trust is the sponsor for this study; it is based in the United Kingdom and will act as the data controller for this study. The day-to-day running of the study is delegated to the Clinical Trials Research Unit in the School of Health and Related Research at The University of Sheffield. Together Sheffield Teaching Hospitals and The University of Sheffield will be using information from you and your medical records in order to undertake this study. This means that we are responsible for looking after your information and using it properly. The University of Sheffield will keep paper copies of identifiable information about you for 10 years after the study has finished and securely store electronic data for a minimum of 10 years. 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. If you withdraw from the study, we will keep the anonymised information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible. You can find out more about how we use your information at https://www.sheffieldclinicalresearch.org/

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). Our Data Protection Officer / The Sponsor's Data Protection Officer is Peter Wilson and you can contact them by phone (0114 2265153) or email (sth.infogov@nhs.net).

[NHS site] will collect information from you and your medical records for this research study in accordance with instructions from Clinical Trials Research Unit at The University of Sheffield.

[NHS site] will use your name, address, email address, telephone number, date of birth to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

Your hospital notes may also be checked. Your GP will be contacted in writing to ask whether your haemorrhoids have come back 1 year after surgery. This will be either by the research nurse within your usual care team, or with your permission, a member of the central research team at the University of Sheffield.

[NHS site] will pass on details from your consent, surgery and the questionnaires you respond to onto the Clinical Trials Research Unit at Sheffield University along with the information collected from you and your medical records. We will ask your permission to store your contact details at the University of Sheffield. Sharing your contact details is optional. Your details would only be used to contact you in the event that your usual care team are unable to fulfil their role in completing the questionnaires with you. If you agree, the only people in Clinical Trials Research Unit at Sheffield University who will have access to information that identifies you will be people involved in the data collection process, for

instance distributing and receiving questionnaires; the people who analyse the information will not be able to identify you or be able to find out your name or contact details.

[NHS site] will keep identifiable information about you from this study for 10 years after the study has finished. All information that is collected about you during the course of this study will be kept strictly confidential and will be held securely in line with the Data Protection Act (2018). Investigations and/or assessments performed as part of this study may return results, which require further follow-up. If we have any concerns about your health then you will be made aware and with your agreement, your GP will be informed and a referral may be made to a medical team who can help with the problem.

Questionnaire and research data collected from you will be anonymised and entered onto a secure server at the University of Sheffield (Prospect). Prospect complies with the Data Protection Act (2018) and uses industry standard techniques to provide security. Only authorised users granted with permissions can access this data.

What will happen with the results of the research study?

The results of the study will be used to standardise surgical procedures for patients with haemorrhoids. These findings will also be published in scientific journals and presented at scientific meetings. The findings will also be made available to patients through patient organisations, health information websites that are open to the public and the media where possible and appropriate. The study website https://www.sheffield.ac.uk/scharr/research/centres/ctru/orion will publish a summary of the results following completion of the study.

What if there is a problem?

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. The researchers contact details are at the end of this information sheet. If you wish to seek advice or reassurance about your own health, then contact your GP.

If you remain unhappy and wish to complain formally, you can do this by contacting the local NHS Patient Services Team:

Address: <insert address>

Telephone: <insert phone number>

Email: <insert email>

If your care team need to know which surgery you received they will be able to access this information from your medical records.

Who is organising and funding the research?

The project is being carried out by a team of researchers from the School of Health and Related Research at the University of Sheffield and Sheffield Teaching Hospital NHS

Foundation Trust. This study is funded by the National Institute for Health Research Health Technology Assessment (project ref NIHR 131861).

Who has ethically reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by London Queen Square Research Ethics Committee ref 21/LO/0762.

Thank you for taking to time to read this information sheet, we hope that it has been helpful in enabling you to decide if you would like to take part in the ORION trial. This information sheet is for you to keep.

For further information or if you have any questions, please find the research team's contact details below:

Local Contact Details:

[Add local NHS Trust details]

Central Office Contact Details:

Orion Trial Study Manager
Clinical Trials Research Unit, School of Health and Related Research
The University of Sheffield
Room 2.13, Innovation centre
C/O 30 Regent St
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S1 4DA

Tel: 0114 222 4027
Email: [insert trial email address]