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For haemorrhoids that are considered appropriate surgery, does radiofrequency ablation reduce short-term pain, and prevent long-term recurrence compared to current recommended interventions?

Submission date	**Recruitment status**	[X] Prospectively registered
17/12/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
17/12/2021	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
06/03/2025	Surgery	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Piles (also referred to as haemorrhoids) are very common and in some cases require surgery. There are multiple types of operations to treat the piles however, none are perfect. Some are good at curing the piles but can leave lasting damage to the body. Others may be less painful but the piles may return. There are 'newer' treatments, but these are more expensive than the traditional treatments.

One new treatment for piles is called radiofrequency ablation. This works by using radio waves that destroy the pile. There has been a small amount of testing done on this new treatment, but more testing is needed. From the testing that has been done, we know that it is safe, not too painful and patients recover from the surgery quickly. However, not enough research has been done on this treatment for us to confirm this. Therefore, the purpose of this study is to test if radiofrequency ablation is at least as good as the traditional surgeries for curing piles and at the same time easier for the patient to recover from. If it is, these results could help inform the NHS that this treatment is worth the money, which could help future patients.

Who can participate?

Adult patients who are going to undergo surgery for piles at NHS hospitals

What does the study involve?

Participants will be randomly assigned to have either the new radiofrequency ablation surgery or whatever other type of operation that the surgeon thinks is best. The patient will not know which surgery they have had. After their surgery, each patient will be followed up at numerous time points, up to a year after surgery, to see how they are recovering.

What are the possible benefits and risks of participating?

There are no guaranteed benefits to participating in this research. Participants will receive the

appropriate health care by their consultant whether they choose to participate in the study or not. We do not know which type of surgery will be better in the long term. This is the reason for doing this research. By taking part in this study, participants will be directly helping us to inform the treatment of future patients diagnosed with haemorrhoids that need surgical treatment. All treatments offered in the trial are routinely offered in the NHS; both would be options offered to participants if they did not take part in the trial and are considered to be safe treatments. Although, RFA is not available in all NHS Trusts. There are possible side effects to all surgical treatment options for haemorrhoids, as well as possible side effects of anesthetic. These are listed in the Participant Information Sheet or by talking to your care team. Participants will be asked to give up some of their time to answer the follow-up questions, they may also be asked some sensitive questions about their symptoms.

Where is the study run from?
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
July 2021 to December 2025

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Prof Steven Brown, steven.brown13@nhs.net
Study Team, orion@sheffield.ac.uk

Study website
https://www.sheffield.ac.uk/scharr/research/centres/ctru/orion

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
300449

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 50709, NIHR131861, IRAS 300449

Study information

Scientific Title
RadiO fRequency ablatION for haemorrhoids (ORION)

Acronym
ORION

Study objectives

Radiofrequency ablation will be non-inferior to other current surgical techniques for treating haemorrhoids, and superior in terms of recurrence and pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/12/2021, London Queen Square REC (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 2071048109; queensquare.rec@hra.nhs.uk), ref: 21/LO/0762

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Haemorrhoid surgery

Interventions
Potential patients will be referred to a NHS recruiting centre for the treatment of grade II/III haemorrhoids.

Potential patients will fall into two groups:
1. Patients that present to the surgical outpatient clinic that have symptomatic haemorrhoids. They will have failed conservative therapies and therefore the treatment suggested would be office therapy such as Rubber Band Ligation (RBL) and would therefore likely be an example of grade II haemorrhoids. If the RBL treatment fails, they will be offered entry into the trial.
2. Patients that present to the surgical outpatient clinic with symptomatic haemorrhoids but are considered unsuitable for office therapies such as RBL. These patients would be considered to have grade III haemorrhoids. They will also have failed conservative therapies. These patients will be offered into the trial.

These patients will be identified and a participant information sheet will be posted to them. The patient will attend an outpatient clinic visit where their eligibility for the trial will be assessed. If the patient chooses to take part, informed consent will be taken by research personnel. If the patient is consented onto the study, baseline measures will be taken via questionnaires asked by the research staff in clinic.

Alternatively, patients can be recruited via postal consent. A PIS will be posted out these patients, in addition to two copies of the postal consent form (one for the patient to keep and one to post back to the research team). Once the patient has read the PIS, after 24 hours, if the patient agrees to take part in the trial, they will sign both copies of the consent form. Once the signed consent form has been returned, a member of the delegated research team will call the patient to complete the postal consent review form. The research team may also call the patient prior to receiving the consent form to answer any questions.

Patients will then be randomised into one of the two treatment groups: Radiofrequency Ablation or the surgeon's choice of treatment (Haemorrhoidectomy, Staple Haemorrhoidpexy or Haemorrhoidal Artery Ligation). The baseline measures asked will be asked on the day of surgery due to the wait time between consent and surgery potentially leading to changes in the patient's responses.

Participants will be asked to complete follow-up questionnaires on day 1, 7 and 21 following their intervention via telephone or postal self-report assessment.

Six weeks after their surgery, participants will attend a routine clinic visit. The timing of this follow-up may vary based upon appointment availability at the individual collaborating centres.

Twelve months after the intervention, the participant will complete the final set of follow-up questionnaires via telephone or postal self-report assessment. Also at twelve months, a member of the research team will write to the participant's GP and check their medical notes for information on further haemorrhoid treatment as a supplement to this follow-up. The patient's surgeon will also be asked about any further treatment.

Intervention Type
Other

Primary outcome measure
1. Recurrence at 12 months post procedure measured using patient records
2. Pain measured by Numeric Pain Rating Scale (NPRS) daily over 7 days post procedure

Secondary outcome measures
1. Pain is measured by the 'Numeric Pain Rating Scale' at baseline (day of surgery), 1 day, 7 days, 21 days 6 week and 1 year post procedure
2. Incontinence score is measured by Vaizey incontinence score baseline (day of surgery), 6 weeks post surgery, 1 year post surgery
3. Quality of life measured by EQ5D: baseline (day of surgery), 1 day, 7 days, 21 days 6 week and 1 year post procedure
4. Severity of haemorrhoid measured by haemorrhoid severity score baseline (day of surgery), 6 weeks post surgery, 1 year post surgery
5. Operation details: day of surgery
6. Recurrence of symptoms measured by complications review interview; 6 weeks post surgery, 1 year post surgery
7. Economic impact: days of work lost questionnaire: 6 weeks post surgery, 1 year post surgery
8. Recurrence of hemorrhoid measured by a triangulation of participant question based on Hubble Trial, surgeons questionnaire and GP questionnaire; week 6 post surgery and 1 year post surgery
9. Haemorrhoid severity measured by clinical appearance at proctoscopy: 6 weeks post surgery

Overall study start date
01/07/2021

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/07/2022:
1. Adults aged 18 years or over with symptomatic grade II or grade III haemorrhoids
2. And patients who have failed conservative management for haemorrhoids (diet and lifestyle changes) and want further intervention
3. And/or patients who have failed either one episode of Rubber Band Ligation (RBL) or have grade III haemorrhoids considered inappropriate for RBL treatment and/or have grade II or III haemorrhoids which the surgeon feels operative intervention is appropriate

Previous inclusion criteria:
1. Adults aged 18 years or over with symptomatic grade II or grade III haemorrhoids
2. And patients who have failed conservative management for haemorrhoids (diet and lifestyle changes) and want further intervention
3. And patients who have failed either one episode of Rubber Band Ligation (RBL) or have grade III haemorrhoids considered inappropriate for RBL treatment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 376; UK Sample Size: 376

Total final enrolment
384

Key exclusion criteria
1. Patients with known perianal sepsis, inflammatory bowel disease, anal or colorectal malignancy, pre-existing sphincter injury
2. Patients with an immunodeficiency (HIV or other medical issue)
3. Patients who are unable to have general or spinal anaesthetic
4. Patients currently taking Warfarin, Clopidogrel or any other hypercoagulability condition
5. Pregnant women
6. Patients with a pacemaker

6. Patients unable to give full informed consent
7. Patients previously randomised to this trial
8. Patients participating in any other clinical trial

Date of first enrolment
01/03/2022

Date of final enrolment
31/01/2024

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Northern General Hospital
Sheffield Teaching Hospitals NHS Foundation Trust
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Queens Hospital
Barking, Havering and Redbridge University Hospitals NHS Trust
Rom Valley Way
Romford
United Kingdom
RM7 0AG

Study participating centre
Darent Valley Hospital
Dartford and Gravesham NHS Trust
Darenth Wood Road
Dartford
United Kingdom
DA2 8DA

Study participating centre
Basingstoke and North Hampshire Hospital
Hampshire Hospitals NHS Foundation Trust
Aldermaston Road
Basingstoke
United Kingdom
RG24 9NA

Study participating centre
Queen Elizabeth Hospital
University Hospitals Birmingham NHS Foundation Trust
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Basildon Hospital
Nethermayne
Basildon
United Kingdom
SS16 5NL

Study participating centre
University College London Hospital
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
Aintree University Hospital
Lower Lane
Liverpool
United Kingdom
L9 7AL

Study participating centre
University Hospital of Wales
Heath Park

Cardiff
United Kingdom
CF14 4XW

Study participating centre
Kings College Hospital
Mapother House
De Crespigny Park
Denmark Hill
London
United Kingdom
SE5 8AB

Study participating centre
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
North Tyneside General Hospital
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Poole Hospital
Longfleet Road
Poole
United Kingdom
BH15 2JB

Study participating centre
Bolton Royal Hospital
Minerva Road
Farnworth

Bolton
United Kingdom
BL4 0JR

Study participating centre
Torbay Hospital
Newton Road
Torquay
United Kingdom
TQ2 7AA

Study participating centre
West Middlesex University Hospital
Twickenham Road
Isleworth
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TW7 6AF

Study participating centre
Leigh Infirmary
The Avenue
Leigh
United Kingdom
WN7 1HS

Study participating centre
Countess of Chester Hospital
Countess of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1UL

Study participating centre
St Helens Hospital
St. Helens Hospital
Marshalls Cross Road
St. Helens
United Kingdom
WA9 3DA

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

Sponsor details
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU
+44 1142265941
dipak.patel12@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.sth.nhs.uk/

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request. The dataset will be stored at the University of Sheffield on a secure network. Details of the data sharing requirements are not yet available. Various details of the dataset will be included in the publication.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	12/11/2021	17/12/2021	No	Yes
Protocol file	version 1.2	15/12/2021	17/12/2021	No	No
Protocol file	version 1.4	19/04/2022	15/07/2022	No	No
Protocol article		09/11/2022	10/11/2022	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 3.2	03/08/2023	01/03/2024	No	No
Statistical Analysis Plan	version 4.0	08/02/2023	01/03/2024	No	No
Protocol file	version 3.3	30/07/2024	06/03/2025	No	No