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Pilonidal sinus treatment studying the options: trial of pit-picking plus fibrin glue vs other minimally invasive surgeries

Submission date
30/09/2026

Recruitment status
Recruiting

Registration date
01/10/2026

Overall study status
Ongoing

Last Edited
01/10/2026

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Pilonidal sinus disease (PSD) is a condition that usually affects the skin just at the top of the buttocks near the tailbone. It is a chronic condition characterised by a small hole, sinus, or cyst that develops in the skin and often becomes infected. Infection will cause pain and swelling in the area and a pus-filled skin abscess can develop.
The cure for PSD usually requires surgery, with two main surgical approaches. One involves removing the affected skin and closing the wound, the other aims to save the skin by using so-called minimally invasive surgery (MIS). The PITSTOP study concluded that the burden after surgery for PSD is high and treatment failure common. MIS may improve outcomes at the expense of a 10% higher risk of treatment failure. The most appropriate treatment depends on the type and severity of a patient's disease, but for those patients who are suitable for MIS, there are several different techniques that can be used.
At the moment, we do not know whether one MIS is better than the other; PITSTOP found that 'Pit picking + glue' is the most common MIS in the UK. In this trial we will compare this technique to other MIS procedures used as standard of care within the UK NHS.

Who can participate?
Patients aged 16 years and over who are undergoing MIS for PSD

What does the study involve?
Participants will be randomly assigned to have either the pit-picking plus glue 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 1 year after surgery, to see how they are recovering.

What are the possible benefits and risks of participating?
Not provided at time of registration

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?
September 2026 to February 2030

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

Who is the main contact?
1. Prof. Steven Brown, steven.brown13@nhs.net
2. Ms Gemma Hackney, PITSTOP2@sheffield.ac.uk

Contact information

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Principal investigator, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
357963

Central Portfolio Management System (CPMS)
68155

National Institute for Health and Care Research (NIHR)
175072

Study information

Scientific Title
Pilonidal sinus treatment studying the options: trial of pit-picking plus fibrin glue vs other minimally invasive surgeries

Acronym
PITSTOP2

Study objectives
1. To compare whether pit picking + glue results in a significantly faster time to return to normal activities than other minimally invasive interventions for PSD
2. To compare whether pit picking + glue results in a similar treatment failure rate to other minimally invasive interventions for PSD
3. To compare outcomes after stratifying into non-complex (non-recurrent disease with pits or sinuses confined to the midline) and complex disease (midline disease with secondary sinus/es or abscess scar/s or any disease after treatment with definitive intent)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/07/2026, North West - Greater Manchester South Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; gmsouth.rec@hra.nhs.uk), ref: 26/NW/0194

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pilonidal sinus disease (PSD)

Interventions
Once eligibility has been confirmed and consent acquired, the participant will be randomly allocated (in a 1:1 ratio) to one of the following groups: intervention (pit picking + glue) or control (surgeon's choice standard of care MIS - pit picking alone, Bascom’s 1, endoscopic pilonidal sinus treatment [EPSIT] or sinus laser assisted closure [SILAC]) using the Sheffield CTRU online randomisation system.

On the day of surgery, baseline measures will be taken and the participant will undergo their intervention. At Day 1, 7 and 21, participants will be asked to complete follow up questionnaires via telephone assessment or online. The 6-week follow-up visit will be in line with the standard of care post-surgical follow up visit for these participants, and will be completed in clinic. At 6 and 12 months, participants will be asked to complete follow up questionnaires by telephone, online or post. At the 12-month visit, disease recurrence will be evaluated by photograph, participants will have the option of either attending the clinic for an in-person follow-up to assess recurrence (if they prefer) or to remotely take a photo of the pilonidal sinus site and upload it to the database for the trial. Further information will be provided to participants who wish to upload photos remotely.

The trial follows the standard pathway for pilonidal disease surgery. All timepoints for data collection will be carried out either electronically, via post or telephone. There is no need for additional clinical appointments other than standard of care.

Intervention Type
Other

Primary outcome(s)
1. Time to return to usual activities after surgery, measured using time to return to pre-illness daily routine without limitation, e.g. return to work or school at pre-illness levels (full/part-time) and/or unrestricted mobility in routine tasks (walking/sitting/stairs) and/or no requirement for regular analgesia beyond paracetamol+/-NSAIDs, reported by the participant.

2. Treatment failure measured using patient report at 6 months. Participants will be asked whether they consider their pilonidal sinus disease cured or sufficiently better to not require further treatment and whether the same or worse than before surgery. Treatment failure will also be considered to have occurred if the patient has had to have a further procedure within that 6-month period.

Key secondary outcome(s)
1. Time over a 12-month period where the patient is unable to do usual activities, measured using participant report
2. Need for further surgery for persistent disease or recurrence by 12 months and end of study, measured using participant report and assessment by colorectal surgeon of disease area
3. Patient-reported treatment failure at 12 months
4. Clinical assessment of recurrence at 12 months and at trial end. Recurrence is defined as disease (midline pits/ulcers +/- lateral extensions) that has healed after surgery and then

recurred at the same site or a new position. This will be assessed by a patient photograph of the site or a clinic appointment (participants choice).
5. Length of stay in hospital, measured using participant medical notes
6. Pain measured using participant-reported questionnaire (Numeric Pain Rating Scale) at days 1, 7 and 21
7. Quality of life measured using EQ-5D-5L at baseline
8. Complications (bleeding, infection, wound dehiscence) reported by participant or from participant's medical notes from day of surgery to 6 weeks post-surgery
9. Health-related quality of life measured using the Cardiff Wound Impact Schedule (CWIS) at 6 and 12 months
10. Health-related quality of life measured using the Health Anxiety Inventory (HAI) at 0, 6 and 12 months
11. Patient health and social care resource use and indirect costs (time off work) measured using participant questionnaire at 0, 6 and 12 months
12. Feasibility outcomes of recruitment % completion, recruitment rate, total recruitment and number of sites open for the internal pilot, reported and reviewed by the central trial management team at month 20 (1 year after recruitment starts)

Completion date
28/02/2030

Eligibility

Key inclusion criteria
1. Adult patients over 16 years old
2. Pilonidal sinus disease (including recurrent disease) where elective minimally invasive surgery (MIS) is planned
3. Able to give informed consent
4. Symptomatic pilonidal sinus disease (pain, discharge, bleeding)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria

1. Acute abscess
2. Hypersensitivity to tissue glue
3. Pregnancy (tested as per routine care)

Date of first enrolment
30/10/2026

Date of final enrolment
31/12/2028

Locations

Countries of recruitment
United Kingdom

England

Scotland

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

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

Study participating centre
Nottingham University Hospitals NHS Trust
Trust Headquarters
Queens Medical Centre
Derby Road
Nottingham
England
NG7 2UH

Study participating centre
Chelsea and Westminster Hospital NHS Foundation Trust
Chelsea & Westminster Hospital
369 Fulham Road
London
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SW10 9NH

Study participating centre
University Hospitals of Derby and Burton NHS Foundation Trust
Royal Derby Hospital
Uttoxeter Road
Derby
England
DE22 3NE

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

Study participating centre
Bolton NHS Foundation Trust
The Royal Bolton Hospital
Minerva Road
Farnworth
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BL4 0JR

Study participating centre
Mersey and West Lancashire Teaching Hospitals NHS Trust
Whiston Hospital
Warrington Road
Prescot
England
L35 5DR

Study participating centre
Wirral University Teaching Hospital NHS Foundation Trust
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Arrowe Park Road
Upton
Wirral
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CH49 5PE

Study participating centre
Somerset NHS Foundation Trust
Trust Management
Lydeard House
Musgrove Park Hospital
Taunton
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TA1 5DA

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
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High Heaton
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NE7 7DN

Study participating centre
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Cobbett House
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M13 9WL

Study participating centre
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Countess of Chester Health Park
Liverpool Road

Chester
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CH2 1UL

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
England
CB2 0QQ

Study participating centre
Tameside and Glossop Integrated Care NHS Foundation Trust
Tameside General Hospital
Fountain Street
Ashton-under-lyne
England
OL6 9RW

Study participating centre
NHS Lothian
Waverley Gate
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Study participating centre
Sherwood Forest Hospitals NHS Foundation Trust
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England
NG17 4JL

Study participating centre
South Tyneside and Sunderland NHS Foundation Trust
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Kayll Road

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SR4 7TP

Study participating centre
Cwm Taf Morgannwg University Local Health Board
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Study participating centre
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Scotland
DD2 1GZ

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NN16 8UZ

Study participating centre
London North West University Healthcare NHS Trust
Northwick Park Hospital
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HA1 3UJ

Study participating centre
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Salford Royal
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M6 8HD

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date