

Pilonidal sinus treatment: studying the options

Submission date 03/12/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/03/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/09/2024	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Pilonidal disease is an infection in the crease of a person's buttocks. The aim of this study is to determine the types of pilonidal disease, to describe the various treatments, to engage with patients and to determine which outcomes they value and which treatments they prefer/do not prefer, and to provide recommendations for further research.

Who can participate?

Patients aged over 16 years with symptomatic pilonidal sinus

What does the study involve?

Before the start of the study there will be a survey circulated within the colorectal consultant surgeon network. This survey will seek to determine the methods of surgery currently employed in the field and the ways in which the surgeon learned this technique. The survey will also explore the factors affecting choice of treatment method in relation to disease presentation. Finally, it will seek to investigate the estimated mean recurrence rate for each surgeon. The study will record details of participants' pit/track anatomy, surgical treatment, medical events, and health-related quality of life until six months after their operation. It will then describe the combination of treatments currently in use and quantify clinical and patient-reported outcomes associated with each. It will also identify patient-specific disease features that might predict poor outcomes in each treatment group. It will then derive an estimate of the risks associated with common treatment options, ranking the best treatment strategies among patients for whom more than one treatment is considered appropriate. The study will then use case-studies to provide an overview of patient views and experiences of the treatment that they have chosen and received. This will also include the views of patients on which treatments they would rather avoid and which outcomes they most value in regards to their treatment options.

What are the possible benefits and risks of participating?

The study is predicted to reach a consensus on which subtypes of pilonidal disease may benefit from which treatment options. Additionally, the research is predicted to reach a surgeon and patient-based consensus on research priorities.

Where is the study run from?

University of Sheffield and 28 sites (UK)

When is the study starting and how long is it expected to run for?
September 2018 to March 2023

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

Who is the main contact?
1. Emily Strong
EmilyStrong@barnsley.gov.uk
2. Prof. Steven Brown
3. Prof Daniel Hind
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Study website
<https://www.sheffield.ac.uk/scharr/research/centres/ctr/pitstop>

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 40221

Study information

Scientific Title
The PITSTOP study: pilonidal sinus treatment: studying the options

Acronym
PITSTOP

Study objectives
This is a prospective cohort study to determine the subtypes of pilonidal disease for which the various treatment options are indicated, to describe the various interventions that are used to treat the disease, to engage with patients and determine which outcomes they value and which interventions they prefer/do not prefer and to provide recommendations for further research.

Ethics approval required

Old ethics approval format

Ethics approval(s)

East of England - Cambridge South Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

26/11/2018, ref: 18/EE/0370

Study design

Observational; Design type: Cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Pilonidal sinus disease

Interventions

Design

1. Survey of consultant surgeons
2. Observational cohort
3. Nested mixed method case study
4. Discrete choice experiment
5. Modified nominal group consensus exercise

1. 1. Survey of consultant surgeons

Prior to the commencement of the cohort study there will be a survey circulated within the colorectal consultant surgeon network. The survey will be distributed via email throughout the trainee surgeon network and will be completed in paper and pencil format by consultant colorectal surgeons. This survey will seek to determine the methods of surgery currently employed in the field and the ways in which the surgeon learned this technique. The survey will also explore the factors affecting choice of treatment method in relation to disease presentation. Finally, it will seek to investigate the estimated mean recurrence rate for each

surgeon. Currently, there is a lack of evidence outlining the general practice of treatment for pilonidal sinus in the UK. This survey will provide evidence on the techniques currently in use in the UK Health Care system.

2. Observational cohort study

Patients considered suitable for surgery will be identified from GP or secondary care referrals, sent a patient information sheet about the study, detailing the study and all treatment options, and diverted preferably to a specific recruiting clinic. At the clinic, a member of the research team will explain the study to the patient and give them the opportunity to ask any questions. The Principal Investigator or delegated research team member will confirm eligibility and ensure written informed consent is obtained before any patient data is collected. Participants will be advised that they are able to withdraw from the study at any point without any impact on their routine NHS care. As is standard practice, the surgeon will discuss the condition, possible interventions and their advantages and disadvantages. Each participant will be invited to answer a questionnaire on shared decision making (CollaboRATE).

Baseline data, taken face to face immediately after consent, will include patient demographics, social and occupation factors, hair and skin type and previous pilonidal surgery history. Pilonidal disease characteristics, recorded by the surgeon immediately post-op will include pit numbers, track numbers, length, unilateral/bilateral distribution, position, presence of pus and previous surgical scarring. Description of the intervention will include all excision and closure techniques used with a description of major steps taken and potential variants thereof. Use of anaesthetic (general, regional, local), period-operative antibiotics, planned post-operative wound care will also be recorded.

A pain numeric rating scale score will be recorded by the patient on day 1 via text reminder. A trained research nurse will collect structured questionnaire data and a pain numeric rating scale by telephone at seven days and six months, but face-to-face at the routine clinic visit at 4-6 weeks post-operatively.

Hospital notes and patient self-report will be used to assess recurrence and complications at six months. A patient regret score will also be collected at 6 months.

Following the six-month assessment all patients will be contacted with a one-off follow-up at the end of the study unless the participant withdraws consent to further follow up or dies before the study completes. Patients will be contacted via email and telephone with a questionnaire incorporating persistence of symptoms. Hospital and GP records will be used to ascertain A&E attendance, repeat/additional procedures and unresolved complications due to PD, and interactions with primary care (GP consultations for PD, practice or district nurse visits for dressings).

For all of the cohort patients, data will be collected to establish which patients have further treatment for recurrent symptoms or complications following their initial procedure. This will be achieved at the six-week clinic visit following the intervention and by interrogating hospital records, asking the patients' consultants, writing to patients' GPs and questioning the patient via telephone interview at 6 months and at the end of the study. At this stage each participant will also be invited to complete a questionnaire on decision regret.

3. Nested mixed method case study

A proportion of patients (at least 20) will be randomly selected using a theoretically based sample and asked to take part in the nested mixed methods substudy. For the participants' comfort and convenience, we will collect data by telephone or Skype. To assess which outcomes

are most valued by patients, and whether there are particular interventions they would rather avoid, the baseline interview guide will adapt key questions from the CODE framework. Interviews will last 15-20 minutes at baseline and 10 minutes at six months.

4. Discrete choice experiment

The data from these interviews will be used to construct a discrete choice experiment. All consented patients will be sent a link to their email addresses via Qualtrics, containing a participant information sheet and simple instructions on how to complete the choice questionnaire. The questionnaire will contain hypothetical choice scenarios (typically range from 8-12 choice sets to avoid cognitive burden) and will ask patients to make choices between two combinations of outcomes with varying levels. The questionnaire should take no more than 15 minutes to complete.

5. Modified nominal group consensus exercise

At the end of the cohort study a consensus regarding the sub-groups of patients for whom the various interventions may be suited will be generated, along with a consensus working with clinicians and patients, together with a consensus meeting defining appropriate comparators and valued outcomes for any future randomised controlled trial. To do this, a modified nominal group technique consensus exercise will be undertaken. This will take place over half a day, adjacent to the annual ACPGBI. It will be opened to around 40 colorectal surgeons and around 15 patients from across the UK.

Intervention Type

Other

Primary outcome measure

As this is a cohort study examining current practice there are no primary outcome measures per se. Identifying appropriate outcome measures for future studies is one of the objectives of the project. The trialists aim to collect the following data:

1. Pain measured using a numeric rating scale at day 1 and day 7 post-operatively. It will also be collected at the routine follow up appointment and at the six month follow up
2. Quality of life measured using the EQ-5D-5L quality of life scale at baseline, at day 7 post operative, at the routine follow up appointment and at the six month follow up
3. Interactions with primary and secondary care asked at day 7 post-operatively, at the routine follow up appointment and at the six month follow up
4. Wound healing and impact measured using the Cardiff Wound Impact Scale at the routine follow up appointment and at the six month follow up
5. Return to normal activities asked using a single question at at baseline, at day 7 post operative, at the routine follow up appointment and at the six month follow up
6. Complications that occur following the intervention identified on the 'Procedure details' CRF and any further complications identified at the six-week clinic visit and at the six-month follow-up
7. Recurrence measured through a single question at an end of study follow up call or through hospital notes

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/09/2018

Completion date

31/03/2023

Eligibility

Key inclusion criteria

Current inclusion criteria as of 04/09/2020:

1. Consenting patients with pilonidal sinus disease that requires surgical intervention
2. Aged over 16 years

Previous inclusion criteria:

1. Consenting patients with pilonidal sinus disease that requires surgical intervention
2. Aged over 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

16 Years

Sex

Both

Target number of participants

Planned Sample Size: 800; UK Sample Size: 800

Total final enrolment

677

Key exclusion criteria

1. Asymptomatic
2. Pregnant
3. Unable to give consent
4. Acute abscess - which is defined as a tender swelling containing pus that presents acutely - the decision on whether or not to operate is at the discretion of the surgeon assessing the patient

Date of first enrolment

01/05/2019

Date of final enrolment

31/03/2022

Locations

Countries of recruitment

England

Scotland

United Kingdom

Wales

Study participating centre

Addenbrooke's Hospital

Hills Rd

Cambridge

United Kingdom

CB2 0QQ

Study participating centre

University Hospital of Wales

Heath Park Way

Cardiff

United Kingdom

CF14 4XW

Study participating centre

Countess of Chester Hospital

Liverpool Rd

Chester

United Kingdom

CH2 1UL

Study participating centre

Royal Derby Hospital

Uttoxeter Rd

Derby

United Kingdom

DE22 3NE

Study participating centre

Glasgow Royal Infirmary

84 Castle St

Glasgow

United Kingdom

G4 0SF

Study participating centre
Leicester General Hospital
Gwendolen Rd
Leicester
United Kingdom
LE5 4PW

Study participating centre
Wirral University Teaching Hospital NHS Foundation Trust (WUTH)
Arrowe Park Hospital
Arrowe Park Rd
Birkenhead
United Kingdom
CH49 5PE

Study participating centre
Manchester Royal Infirmary
Oxford Rd
Manchester
United Kingdom
M13 9WL

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Ln
Norwich
United Kingdom
NR4 7UY

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Queen Alexandra Hospital

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Portsmouth
United Kingdom
PO6 3LY

Study participating centre
St. Mark's Hospital
Watford Rd
Harrow
United Kingdom
HA1 3UJ

Study participating centre
Northern General Hospital
Glossop Rd
Sheffield
United Kingdom
S10 2JF

Study participating centre
Western General Hospital
Crewe Rd S
Edinburgh
United Kingdom
EH4 2XU

Study participating centre
Tameside and Glossop Integrated Care NHS Foundation Trust
Fountain St
Ashton-under-Lyne
United Kingdom
OL6 9RW

Study participating centre
Newcastle Upon Tyne Hospitals NHS Foundation Trust
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
York Teaching Hospital NHS Foundation Trust
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
St Helens and Knowsley Teaching Hospitals NHS Trust
Whiston Hospital
Warrington Road
Prescot
United Kingdom
L35 5DR

Study participating centre
Morriston Hospital
Heol Maes Eglwys
Morriston
Cwmrhydyceirw
Swansea
United Kingdom
SA6 6NL

Study participating centre
Salford Royal NHS Foundation Trust
Stott Ln
Salford
United Kingdom
M6 8HD

Study participating centre
Yeovil District Hospital NHS Foundation Trust
Higher Kingston
Yeovil
United Kingdom
BA21 4AT

Study participating centre

Musgrove Park Hospital

Parkfield Dr

Taunton

United Kingdom

TA1 5DA

Study participating centre**Queen Elizabeth The Queen Mother Hospital**

St Peter's Rd

Margate

United Kingdom

CT9 4AN

Study participating centre**Royal Devon & Exeter NHS Foundation Trust**

Exeter

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Study participating centre**East Suffolk and North Essex NHS Foundation Trust**

Heath Rd

Ipswich

United Kingdom

IP4 5PD

Study participating centre**Basingstoke and North Hampshire Hospital**

Hampshire Hospitals NHS Foundation Trust

Aldermaston Road

Basingstoke

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Study participating centre**Queens Hospital**

Burton Upon Trent

United Kingdom

DE13 0RB

Sponsor information

Organisation

Sheffield Teaching Hospitals NHS Foundation Trust

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United Kingdom
S10 2SB

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modhumita.harris@sth.nhs.uk

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/018hjpz25>

Funder(s)

Funder type

Government

Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 17/17/02

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/01/2024

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Basic results		21/03/2024	28/03/2024	No	No
Results article		24/07/2024	25/07/2024	Yes	No
Results article	Decisional regret	25/09/2024	26/09/2024	Yes	No