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Pilonidal sinus treatment: studying the options

Submission date
03/12/2018

Recruitment status
No longer recruiting

Registration date
26/03/2019

Overall study status
Completed

Last Edited
26/09/2024

Condition category
Infections and Infestations

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] 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 particpants' 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 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
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2. Prof. Steven Brown
3. Prof Daniel Hind
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Public

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Additional identifiers

Central Portfolio Management System (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

Primary study design
Observational

Study design
Observational; Design type: Cohort study

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

16 Years

Sex
All

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
United Kingdom

England

Scotland

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
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United Kingdom
OX3 9DU

Study participating centre
Queen Alexandra Hospital
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Portsmouth
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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
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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
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Newcastle upon Tyne
United Kingdom
NE7 7DN

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

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

Study participating centre
Morriston Hospital
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Cwmrhydyceirw
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SA6 6NL

Study participating centre
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Stott Ln
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M6 8HD

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Musgrove Park Hospital
Parkfield Dr
Taunton
United Kingdom
TA1 5DA

Study participating centre
Queen Elizabeth The Queen Mother Hospital
St Peter's Rd
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CT9 4AN

Study participating centre
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Exeter
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EX2 5DW

Study participating centre
East Suffolk and North Essex NHS Foundation Trust
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IP4 5PD

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

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

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?
Results article		24/07/2024	25/07/2024	Yes	No
Results article	Decisional regret	25/09/2024	26/09/2024	Yes	No
Basic results		21/03/2024	28/03/2024	No	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes