ISRCTN32116071 https://doi.org/10.1186/ISRCTN32116071

PROPHER: Quality-of-life feedback using patient-reported outcomes after treatment of parastomal hernia

Submission date 17/07/2023	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 17/08/2023	**Overall study status** Ongoing	
Last Edited 06/08/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
PROPHER stands for Patient Reported Outcomes after Parastomal Hernia Treatment. The overall aim of the PROPHER study is to see what the impact on the patient's quality of life is from having treatment for a parastomal hernia. The study will also look at how parastomal hernias are treated, for example having an operation and any complications that happen in the first 30 days, or deciding to "watch and wait". It will also look at whether there are any links between the way that a surgeon repairs a parastomal hernia and the outcomes.

What is a parastomal hernia? Stoma formation is often necessary after bowel surgery. A common complication of a stoma is a parastomal hernia (PSH), caused by a weakness in the abdominal muscle which results in a local bulge next to or behind the stoma. A PSH can cause skin irritation, problems with getting a stoma bag to stick, as well as pain and other more serious complications such as bowel obstruction. These issues often have a negative impact on a patient's quality of life.

What are patient-reported outcomes? Patient-reported outcome measures (PROMs) are questionnaires that measure the patient's view of their own health. Questionnaires are completed before and after treatment so that healthcare professionals and researchers can see how the treatment has impacted the patient.

Who can participate?
Patients aged 18 years or above with a symptomatic parastomal hernia. This includes those referred to a colorectal surgeon for consideration of surgical treatment or seen by a clinical nurse specialist. Patients undergoing surgical treatment or conservative/watchful waiting are eligible for entry.

What does the study involve?
Participants will be asked to complete questionnaires about their parastomal hernia as well as information about how they feel at various stages throughout their treatment. These details will be collected at the start (baseline), at 3 months, 6 months and at 12 months. The hospital team

will also record some additional information about the participant's medical history, and if patients have an operation as part of their treatment, they will record details about the surgery.

What are the possible benefits and risks of participating?
We do not expect any risk to study participants. Joining the study will not have any impact on patient care as participants will be receiving the same treatment they would if they did not join the study. Participants might find messages reminding them to complete the questionnaires a minor inconvenience, given that the study follow-up period continues up to 12 months after joining the study.
There will not be any direct personal benefit to joining the study. However, the data collected from the study will translate into direct benefits for patients in the future. It is possible that a patient participating in PROPHER will not achieve successful PSH treatment during the lifetime of the study, or they will develop a new or recurrent PSH in the future. As such, an individual may also be able to personally benefit from their involvement in the study.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
March 2021 to August 2030

Who is funding the study?
Bowel Research UK and the European Society of Coloproctology (ESCP)

Who is the main contact?
Miss Nyesha Henry, n.henry.1@bham.ac.uk

Study website
https://www.escp.eu.com/research/cohort-studies/2019-patient-reported-outcomes-after-parastomal-hernia-treatment

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
298207

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52007, BRUK334, IRAS 298207

Study information

Scientific Title
Patient Reported Outcomes after parastomal hernia treatment - a prospective international cohort study

Acronym
PROPHER

Study objectives
A prospective international cohort study of parastomal hernia (PSH) treatment, including both operative and non-operative interventions. A global network of clinicians and specialist nurses will collate detailed information on individual interventions used and short-term outcomes, then patients will provide their own medium and longer-term outcomes data including whether their treatment was successful, via a secure online/mobile phone-based system. The study will provide a wealth of contemporaneous information which will improve our ability to counsel patients and facilitate improved selection of appropriate and personalised interventions for those with a PSH.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/04/2022, South Central - Hampshire B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8064; hampshireb.rec@hra.nhs.uk), ref: 22/SC/0060

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital, Internet/virtual, Medical and other records

Study type(s)
Quality of life

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Parastomal hernia (PSH)

Interventions
PROPHER is an international multi-centre prospective cohort study. A global network of clinicians and specialist nurses will enrol adults over the age of 18 years with a symptomatic parastomal hernia (PSH) for which treatment or intervention is being sought. the study is observational only - no intervention will be decided by the study protocol and is instead as per treating clinician's decision.

Patients undergoing both operative and non-operative interventions will be included, and identical outcome measures obtained for both populations. These outcome measures of treatment success will be almost exclusively patient-reported up to one year after study and include quality of life, stoma-specific symptom scores and additional treatments including hospital admission. In addition, a modified MYMOP (Measure Yourself Medical Outcomes Profile) will be obtained at study entry and this entirely personalised outcome measure assessed individually at study exit (12 months). A decisional regret analysis will also be obtained at study exit.

Patients undergoing surgical intervention during the study period will have additional detailed information recorded about the operative techniques employed so we can assess any impacts, beneficial or otherwise, on patient-reported outcomes. If a patient in the conservative management arm undergoes surgical repair of their parastomal hernia during the 12-month follow-up period, they will automatically cross over into the surgical group.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
This study will collect a range of clinical and patient-reported outcome measures. There is no explicit primary outcome measure.

Patient-reported outcomes:
1. Health-related quality of life reported by the participant using the SF-12 score at baseline and 3, 6 and 12 months post-enrolment
2. Stoma impact reported by the participant using the Stoma Impact Score at baseline and 3, 6 and 12 months post-enrolment
3. Impact of the key symptom or issue the patient is hoping will be improved by their PSH treatment assessed using the modified Measure Yourself Medical Outcomes Profile (MYMOP) at baseline and 12 months post-enrolment
4. Decisional regret assessed using the Decision Regret Scale at 12 months post-enrolment

Clinician-reported outcomes based on routinely collected data held in patient notes transcribed into electronic case report forms (eCRFs):
1. Patient demographics – including BMI, smoking status and comorbidities assessed using the online case report form (CRF) for the study at baseline
2. PSH details - including index operation, PSH characteristics and symptoms, previous treatments for this PSH - assessed using the online CRF at baseline
3. In those undergoing surgical repair:
3.1. Operation details – including technique employed, type and location of mesh placement (if appropriate) assessed using the online CRF at time of surgery
3.2. Short-term post-operation details assessed using the online CRF up to 30 days post-surgery, including:
3.2.1. Postoperative complications assessed using the Clavien-Dindo Scale
3.2.2. Postoperative complications assessed using the comprehensive complication index (CCI)
3.2.3. Length of stay
3.2.4. Unplanned re-operation
4. In those undergoing non-operative management:
4.1. Details of conservative treatment instigated, including support wear, physiotherapy, other advice given assessed using the online CRF at baseline

Secondary outcome measures
There are no additional outcome measures

Overall study start date
01/03/2021

Completion date
15/08/2030

Eligibility

Key inclusion criteria

1. Adult, aged 18 years and above.
2. A stoma formed from any part of the bowel – whole small bowel and colon, and of any format – including loop, end, double barreled, Abcarian, other
3. All treatments for PSH, including conservative (non-operative) treatment and surgical intervention. All types of surgical approach are included.
4. Elective presentations to outpatient services, including surgical, colorectal, stoma care team are included. Patients presenting primarily as an emergency with a symptomatic PSH requiring urgent intervention are also eligible for inclusion, providing informed consent can be obtained.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 1500; UK Sample Size: 500

Key exclusion criteria
1. Patients with an isolated urostomy
2. Life expectancy less than 12 months
3. Proposed treatment plan for dealing with PSH involves restoration of gut continuity meaning that patient will have no stoma after treatment.
4. Anyone who does not have an email address or does not have access to the internet or a smart device

Date of first enrolment
21/08/2023

Date of final enrolment
09/08/2027

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Elizabeth Hospital Birmingham
Mindelsohn Way
Edgbaston

Birmingham
United Kingdom
B15 2WB

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Royal Lancaster Infirmary
Medical Wards
Ashton Road
Lancaster
United Kingdom
LA1 4RP

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Salisbury District Hospital
Salisbury District Hospital
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
Stoke Mandeville Hospital
Mandeville Road
Aylesbury
United Kingdom
HP21 8AL

Study participating centre
York Hospital
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
Bedford Hospital South
Kempston Road
Bedford
United Kingdom
MK42 9DJ

Study participating centre
Broomfield Hospital
Court Road
Broomfield
Chelmsford
United Kingdom
CM1 7ET

Study participating centre
Northern General Hospital
Northern General Hospital NHS Trust
C Floor, Huntsmnan Building
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
University Hospital Coventry & Warwickshire
Clifford Bridge Road
Walsgrave
Coventry
United Kingdom
CV2 2DX

Study participating centre
Warwick Hospital
Lakin Road
Warwick
United Kingdom
CV34 5BW

Study participating centre
Royal Cornwall Hospital (treliske)
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
Blackpool Victoria Hospital
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre
Russells Hall Hospital
Pensnett Road
Dudley
United Kingdom
DY1 2HQ

Study participating centre
Darent Valley Hospital
Darenth Wood Road

Dartford
United Kingdom
DA2 8AA

Study participating centre
Milton Keynes University Hospital
Milton Keynes Hospital
Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
Scarborough General Hospital
Woodlands Drive
Scarborough
United Kingdom
YO12 6QL

Study participating centre
Tunbridge Wells Hospital
The Tunbridge Wells Hospital
Tonbridge Road
Pembury
Tunbridge Wells
United Kingdom
TN2 4QJ

Study participating centre
Salford Royal Hospital
Stott Lane
Eccles
Salford
United Kingdom
M6 8HD

Study participating centre
Royal Blackburn Hospital
Haslingden Road
Blackburn

United Kingdom
BB2 3HH

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

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Luton and Dunstable University Hospital
Lewsey Road
Luton
United Kingdom
LU4 0DZ

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

Study participating centre
Bristol Royal Infirmary
Marlborough Street
Bristol
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BS2 8HW

Sponsor information

Organisation
University of Birmingham

Sponsor details
Edgbaston
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United Kingdom
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Sponsor type
Hospital/treatment centre

Website
http://www.birmingham.ac.uk/index.aspx

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Bowel Research UK

Alternative Name(s)
Bowel Research United Kingdom, BRUK

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
European Society of Coloproctology

Alternative Name(s)
The European Society of COLOPROCTOLOGY, European Society of Coloprotology, ESCP

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal around one year after the study end date. We will also publicise the results on the study's website: https://www.escp.eu.com/research/cohort-studies/2019-patient-reported-outcomes-after-parastomal-hernia-treatment. No individual patients will be identifiable in any publications.

Intention to publish date
15/08/2029

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?
Participant information sheet	version 5.0	21/06/2023	03/08/2023	No	Yes