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UK cohort study to investigate the prevention of parastomal hernia

Submission date 27/11/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 01/02/2018	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 27/09/2024	**Condition category** Surgery	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

During abdominal surgery, it is sometimes necessary to create a stoma (an opening) to divert faeces from the bowel into an external pouch or bag. Unfortunately, the formation of the stoma can be associated with future complications, including the risk of developing a parastomal hernia (PSH). A PSH is an incisional hernia, immediately adjacent and related to the stoma that occurs when the fascia (a band of connective tissue) in the abdominal wall splits. Contents of the abdomen, e.g. fatty tissue or intestine, can be forced through the split in the fascia causing a bulge in the skin. PSH are relatively common and affect approximately 40% of patients within 2 years of their bowel surgery. Complications of PSH can be severe and are known to negatively influence patients' quality of life. Specifically, PSH can make it difficult to attach stoma bags which can cause the bag contents to leak and smell, irritate the surrounding skin and make patients anxious and avoid social situations. PSH can also cause pain and serious problems, e.g. bowel obstruction, which need emergency treatment in hospital. PSH are difficult to manage and in most cases treatment involves specialist stoma care with expensive appliances. In some cases, a surgeon may reoperate to repair the hernia but additional surgery is risky and recurrence of a hernia is not uncommon. Therefore, it is very important to prevent a PSH forming in the first place. Both patient and surgical factors are believed to influence the development of PSH. Of the surgical factors, the size and shape of the incision in the body wall, the use of mesh when the stoma is formed and, if mesh is used, exactly how it is used, have all been described as potentially important considerations. However, the way in which surgeons create stomata is very varied and research is needed to investigate whether these factors influence the risk of developing a PSH. The aim of this study is to establish the incidence of PSH over a period of two years and to evaluate the effects of key technical surgical steps that influence the risks of PSH formation.

Who can participate?

Adults aged 18 and older who are undergoing a surgery to create a stoma.

What does the study involve?

Participants are approached about the study before their surgery by a stoma care nurse or other appropriately trained and qualified member of the direct care team and given a patient information leaflet. Once the participant has consented, baseline details will be collected prior

to their surgery and the participant is asked to complete a baseline questionnaire. Details about their surgery are collected by the surgical team in theatre. Post-operative data is collected by the stoma care nurses or research nurses at discharge. Participants are asked to complete questionnaires at set intervals (about 6 weeks after surgery and then at 6, 12, 18 and 24 months after surgery). Participants are given the option to complete the questionnaires by post or online. If the participant agrees, they may continue to complete the 6 monthly questionnaires up to the end of the whole study period (at 30, 36, 42 and 48 months after surgery). The questionnaires include quality of life questionnaires and questionnaires about symptoms relating to their stoma. Participants are also asked if they have been admitted to hospital or had a CT scan since their last questionnaire. Any CT scans the participant has had are requested from the hospital and reviewed by surgical trainees. Participants also consent for details to be collected from NHS Digital and databases containing records of contacts with stoma care nurses and stoma products prescribed periodically throughout the study.

What are the possible benefits and risks of participating?
There are no direct benefits or risks with participating. This is because nothing about their operation or aftercare will change. We simply wish to collect details about their surgery and recovery to better understand why some patients develop parastomal hernias and others do not. This information will be very useful to the NHS and future patients.

Where is the study run from?
This study is being run by University of Bristol (UK) and takes place in hospitals in the UK.

When is the study starting and how long is it expected to run for?
October 2016 to January 2024

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

Who is the main contact?
Miss Lucy Ellis (Scientific)
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Contact information

Type(s)
Scientific

Contact name
Miss Lucy Ellis

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https://orcid.org/0000-0001-8179-5172

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CPMS 35821

Study information

Scientific Title
The CIPHER study: UK Cohort study to Investigate the prevention of Parastomal HERnia

Acronym
The CIPHER study

Study objectives
Current study hypothesis as of 30/04/2024:

The CIPHER study aims to establish the incidence of symptomatic and clinically confirmed PSH during a minimum of 2 years follow up. Additionally, CIPHER aims to evaluate the effects of key technical surgical steps during index stoma formation on the risk of subsequent PSH formation.

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Previous study hypothesis:

The CIPHER study aims to establish the incidence of symptomatic and radiologically confirmed PSH during a minimum of 2 years follow up. Additionally, CIPHER aims to evaluate the effects of key technical surgical steps during index stoma formation on the risk of subsequent PSH formation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Black Country Research Ethics Committee, 08/11/2017, ref: 17/WM/0401

Study design
Observational 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
Colorectal surgery for hernia

Interventions
Once a participant has consented, baseline details are collected prior to their index surgery and the participants are asked to complete a baseline questionnaire. Intra-operative details are collected by the surgical team. Post-operative data is collected at discharge. Participants are followed up for a minimum of 2 years post index surgery and are asked to complete questionnaires at set intervals (about 6 weeks after surgery and then 6, 12, 18 and 24 months after surgery). Participants have the option to complete the questionnaire by post or online. If the participant agrees, they may continue to complete the 6 monthly questionnaires up to the end of the whole study period (maximum 4 years).

The questionnaires include quality of life questionnaires (EQ-5D-5L & SF-12) and questionnaires to ascertain symptoms of PSH. Participants are also asked if they have been admitted to hospital or had a CT scan since their last questionnaire. Any CT scans are requested from the hospital and reviewed by surgical trainees to ascertain whether PSH is radiologically evident.

Participants consent for details to be collected from NHS Digital and databases containing records of contacts with stoma care nurses and stoma products prescribed periodically throughout the study. Patient involvement in the study finishes once all questionnaires have been submitted.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 30/04/2024:

PSH incidence during follow-up after index surgery to form a stoma (an incident PSH is defined as symptoms of PSH and clinical PSH) are assessed using a custom-designed questionnaire and participants' reports of having "been told by a nurse or doctor that you have a parastomal hernia" at 6, 12, 18 and 24 months after surgery.

Previous primary outcome measure:

PSH incidence during follow-up after index surgery to form a stoma (an incident PSH is defined as symptoms of PSH and anatomical PSH) are assessed using a custom-designed questionnaire and CT scans at 6 weeks and 6, 12, 18 and 24 months after surgery.

Secondary outcome measures
Current secondary outcome measures as of 08/09/2021:

1. Intensive care unit (ICU) stay (days) are recorded during admission for index surgery
2. Hospital stay (days) are recorded during admission for index surgery
3. Surgical site infection is measured using a questionnaire during admission for index surgery and 30 days afterward
4. Other complications are documented using the Clavien Dindo classification and the Comprehensive Complication Index at discharge
5. Symptoms of PSH are measured using a questionnaire at 12 months after index surgery
6. Generic health status is assessed using the EQ-5D-5L, SF12 scales at baseline and follow up time points: 6 weeks, 6, 12, 18, and 24 months after index surgery
7. Appointments with SCNs and advice about stoma care products
8. PSH repair is assessed using procedure codes for stoma formation in HES, information from SCNs
9. Health and social care resource use is measured using HES data at the end of the study
10. PSH identified from CT scan assessment by surgical trainees if CT scan is reported by participants in questionnaires at 6 weeks, 6, 12, 18, and 24 months after index surgery

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Previous secondary outcome measures:

1. Intensive care unit (ICU) stay (days) are recorded during admission for index surgery
2. Hospital stay (days) are recorded during admission for index surgery
3. Surgical site infection is measured using a questionnaire during admission for index surgery and 30 days afterwards
4. Other complications are documented using the Clavien Dindo classification and the Comprehensive Complication Index at discharge
5. Symptoms of PSH are measured using a questionnaire at 12 months after index surgery
6. Generic health status is assessed using the EQ-5D-5L, SF12 scales at baseline and follow up time points: 6 weeks, 6, 12, 18 and 24 months after index surgery
7. Appointments with SCNs and advice about stoma care products
8. PSH repair is assessed using procedure codes for stoma formation in HES, information from SCNs
9. Health and social care resource use is measured using HES data at the end of the study

Overall study start date
01/10/2016

Completion date
29/01/2024

Eligibility

Key inclusion criteria

1. Aged 18 years or over
2. Able to give written informed consent
3. Undergoing elective or expedited surgery to create a stoma; either an ileostomy or colostomy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 4000; UK Sample Size: 4000

Total final enrolment
2500

Key exclusion criteria
Current exclusion criteria as of 19/12/2018:
1. Lacking the capacity to consent
2. Having emergency surgery
3. Previous abdominal wall stoma
4. Life expectancy <12 months from the index procedure
5. Having surgery with intention of forming a double-barrelled stoma
6. Having surgery with intention of forming a urostomy

Previous exclusion criteria:
1. Lacking the capacity to consent
2. Having emergency surgery
3. Previous abdominal wall stoma
4. Life expectancy <12 months from the index procedure
5. Having surgery with the intention of forming a loop ileostomy
6. Having surgery with intention of forming a double-barrelled stoma
7. Having surgery with intention of forming a urostomy

Date of first enrolment
11/12/2017

Date of final enrolment
30/06/2021

Locations

Countries of recruitment

England

Scotland

United Kingdom

Wales

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
Royal Devon University NHS Ft
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
University Hospital Bristol NHS Foundation Trust
Upper Maudlin Street
Bristol
United Kingdom
BS2 8HW

Study participating centre
North Bristol NHS Trust
Southmead Road
Bristol
United Kingdom
BS10 5NB

Study participating centre
Royal Cornwall Hospitals NHS Trust
Treliske
Truro
United Kingdom
TR1 3LQ

Study participating centre
Yeovil District Hospital NHS Foundation Trust
Yeovil Hospital
Higher Kingston

Yeovil
Somerset
United Kingdom
BA21 4AT

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

Study participating centre
Salisbury NHS Foundation Trust
Salisbury District Hospital
Salisbury
Wiltshire
United Kingdom
SP2 8BJ

Study participating centre
University Hospitals of Morecambe Bay NHS Foundation Trust
Westmorland General Hospital
Burton Road
Kendal
United Kingdom
LA9 7RG

Study participating centre
Doncaster & Bassetlaw Teaching Hospitals NHS Foundation Trust
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
South Yorkshire
United Kingdom
DN2 5LT

Study participating centre

North West Anglia NHS Foundation Trust
Peterborough City Hospital
Bretton Gate
Bretton
Peterborough
United Kingdom
PE3 9GZ

Study participating centre
Basildon and Thurrock University Hospitals NHS Foundation Trust
Nether Mayne
Basildon
United Kingdom
SS16 5NL

Study participating centre
Blackpool Teaching Hospitals NHS Foundation Trust
Blackpool Victoria Hospital
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre
Queen Elizabeth Hospital King's Lynn NHS Foundation Trust
Gayton Road
King's Lynn
United Kingdom
PE30 4ET

Study participating centre
East Lancashire Hospitals NHS Trust
Royal Blackburn Teaching Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
Sherwood Forest Hospitals NHS Foundation Trust
Sherwood Forest Hospitals

King's Mill Hospital
Mansfield Road
Sutton in Ashfield
United Kingdom
NG17 4JL

Study participating centre
Warrington and Halton Hospitals NHS Foundation Trust
Warrington Hospital
Lovely Lane
Warrington
United Kingdom
WA5 1QG

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
University Hospital
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
East Kent Hospitals University NHS Foundation Trust
Kent and Canterbury Hospital
Ethelbert Road
Canterbury
United Kingdom
CT1 3NG

Study participating centre
Royal Surrey County Hospital NHS Foundation Trust
Royal Surrey County Hospital
Egerton Road
Guildford
United Kingdom
GU2 7XX

Study participating centre
Manchester University NHS Foundation Trust (Wythenshawe Hospital)
Wythenshawe Hospital

Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
Manchester University NHS Foundation Trust (Manchester Royal Infirmary)
Manchester Royal Infirmary
Oxford Rd
Manchester
United Kingdom
M13 9WL

Study participating centre
East and North Hertfordshire NHS Trust
Lister Hospital
Coreys Mill Lane
Stevenage
United Kingdom
SG1 4AB

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

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

Study participating centre
Countess of Chester Hospital NHS Foundation Trust
The Countess Of Chester Health Park

Chester
United Kingdom
CH2 1UL

Study participating centre
Plymouth Hospitals NHS Trust
Derriford Road
Crownhill
Plymouth
United Kingdom
PL6 8DH

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

Study participating centre
Colchester Hospital University NHS Foundation Trust
Colchester Hospital
Turner Road
Colchester
United Kingdom
CO4 5JL

Study participating centre
East Cheshire NHS Trust
Macclesfield District General Hospital
Victoria Rd
Macclesfield
United Kingdom
SK10 3BL

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital Birmingham
Mindelsohn Way

Edgbaston
Birmingham
United Kingdom
B15 2GW

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

Study participating centre
Mid Cheshire Hospitals NHS Foundation Trust
Leighton Hospital Middlewich Road
Crewe
Cheshire
United Kingdom
CW1 4QJ

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

Study participating centre
North Tees and Hartlepool NHS Foundation Trust
Hardwick Road
Stockton on Tees
Cleveland
United Kingdom
TS19 8PE

Study participating centre
University Hospital of Wales Cardiff
Heath Park

Cardiff
United Kingdom
CF14 4XW

Study participating centre
Kingston Hospital NHS Foundation Trust
Galsworthy Road
Kingston upon Thames
United Kingdom
KT2 7QB

Study participating centre
United Lincolnshire Hospitals NHS Trust
Pilgrim Hospital Boston
Sibsey Road
Boston
United Kingdom
PE21 9QS

Study participating centre
Chesterfield Royal Hospital NHS Foundation Trust
Calow
Chesterfield
United Kingdom
S44 5BL

Study participating centre
Croydon Health Services NHS Trust
530 London Road
Thornton Heath
Croydon
United Kingdom
CR7 7YE

Study participating centre
Ipswich Hospital NHS Trust
Heath Road
Ipswich
United Kingdom
IP4 5PD

Study participating centre
London North West Healthcare NHS Trust
St. Mark's Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
South Wharf Road
St Mary's Hospital
London
United Kingdom
W2 1NY

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

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

Study participating centre

Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

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

Study participating centre
Ashford and St Peter's Hospitals NHS Foundation Trust
St Peter's Hospital
Guildford Road
Chertsey
United Kingdom
KT16 0PZ

Study participating centre
Stockport NHS Foundation Trust
Stepping Hill Hospital
Poplar Grove
Hazel Grove
Stockport
United Kingdom
SK2 7JE

Study participating centre
Derby Teaching Hospital NHS Foundation Trust
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre

City Hospitals Sunderland NHS Foundation Trust
Sunderland Royal Hospital
Kayll Rd
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Mid Yorkshire Hospital NHS Trust
Pinderfields Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Raigmore Hospital Inverness (NHS Highland)
Old Perth Road
Inverness
United Kingdom
IV2 3UJ

Study participating centre
Royal Alexandra Hospital Paisley (NHS Greater Glasgow & Clyde)
Castlehead
Paisley
United Kingdom
PA2 9PJ

Study participating centre
Wrightington Wigan and Leigh NHS Foundation Trust
Wrightington Hospital
Hall Lane
Appley Bridge
Wigan
United Kingdom
WN6 9EP

Study participating centre
Gateshead Health NHS Foundation Trust
Fontwell Dr

Gateshead
United Kingdom
NE8 4YL

Study participating centre
Great Western Hospitals NHS Foundation Trust
Marlborough Road
Swindon
United Kingdom
SN3 6BB

Study participating centre
Heart of England NHS Foundation Trust
Bordesley Green East
Birmingham
United Kingdom
B9 5SS

Study participating centre
Nottingham University Hospitals NHS Trust
Queen's Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Morriston Hospital Swansea (ABM University Health Board)
Heol Maes Eglwys Morriston
Cwmrhydyceirw
Swansea
United Kingdom
SA6 6NL

Study participating centre
Leeds Teaching Hospitals NHS Trust
St James's Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Portsmouth Hospitals NHS Trust
Queen Alexandra Hospital
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
University Hospitals Derby and Burton NHS FT
Queens hospital
Belvedere Rd
Burton-on-Trent
United Kingdom
DE13 0RB

Study participating centre
University Hospitals Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Aintree University Hospitals NHS Foundation Trust
Lower Lane
Fazakerley
Liverpool
United Kingdom
L9 7AL

Study participating centre
Glasgow Royal Infirmary (NHS Greater Glasgow and Clyde)
84 Castle Street
Glasgow
United Kingdom
G4 0SF

Study participating centre
Calderdale and Huddersfield NHS Foundation Trust
Huddersfield Royal Infirmary
Acre Street
Lindley
Huddersfield
United Kingdom
HD3 3EA

Study participating centre
The Royal Wolverhampton NHS Trust
New Cross Hospital
Wolverhampton Road
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Dorset County Hospital NHS Foundation Trust
Williams Avenue
Dorchester
United Kingdom
DT1 2JY

Study participating centre
Worcestershire Acute Hospitals NHS Trust
Charles Hastings Way
Worcester
United Kingdom
WR5 1DD

Study participating centre
Western General Hospital Edinburgh (NHS Lothian)
Crewe Rd S
Edinburgh
United Kingdom
EH4 2XU

Study participating centre

Chelsea and Westminster Hospital NHS Foundation Trust
Chelsea and Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester General Hospital
Gwendolen Road
Leicester
United Kingdom
LE5 4PW

Study participating centre
The Christie NHS Foundation Trust
Wilmslow Road
Manchester
United Kingdom
M20 4BX

Study participating centre
South Warwickshire NHS Foundation Trust
Warwick Hospital
Lakin Road
Warwick
United Kingdom
CV34 5BW

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

Study participating centre

Gloucestershire Hospitals NHS Foundation Trust
Gloucestershire Royal Hospital
Great Western Road
Gloucester
United Kingdom
GL1 3NN

Study participating centre
George Elliot Hospital NHS Trust
George Eliot Hospital
College Street
Nuneaton
United Kingdom
CV10 7DJ

Study participating centre
Medway NHS Foundation Trust
Medway Maritime Hospital
Windmill Road
Gillingham
United Kingdom
ME7 5NY

Sponsor information

Organisation
Royal Devon University Healthcare NHS Foundation Trust

Sponsor details
Royal Devon & Exeter Hospital
Barrack Road
Exeter
England
United Kingdom
EX2 5DW

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type

Government

Funder Name
National Institute for Health 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

Publication and dissemination plan
The findings will be presented at national/international conferences, published in peer-reviewed academic journals, professional media (e.g. to SCNs) and accessible formats in newsletters to patients, in accordance with advice from the PPI group about how best to do this effectively. The findings will also be reported as a briefing paper to commissioners (e.g. commissioning groups, NICE) and to other health care stakeholders with an interest in the research.

Intention to publish date
01/04/2026

Individual participant data (IPD) sharing plan
The study data may be shared for other research (by researchers in NHS or academic institutions) relating to patients who have stomas at any time, providing the data are used for objectives that do not overlap with the CIPHER study objectives. Data relating to CIPHER study objectives may be shared for secondary research after the publication of the main results. NHS digital data (HES data) will not be shared. Data will only be shared where participants have agreed for it to be used in future ethically approved research. In all instances, sharing of anonymised individual patient data should be conditional on assurance from the researcher that the proposed use of the data is compliant with the MRC Policy on Data Preservation and Sharing regarding scientific quality, ethical requirements and value for money. A minimum requirement with respect to scientific quality will be a publicly available pre-specified protocol describing the purpose, methods and analysis of the research, e.g. a study protocol or a protocol for a Cochrane systematic review. The second file containing patient identifiers would be made available for record linkage or a similar purpose, subject to confirmation that the secondary research protocol has been approved by a UK REC or other similar, approved ethics review body.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/07/2021	09/06/2021	Yes	No
Other publications	What should be included in case report forms? Development and application of novel methods to inform surgical study design: a mixed methods case study in parastomal hernia prevention	05/10/2022	06/10/2022	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version 5.0	05/01/2024	30/04/2024	No	No