

# UK cohort study to investigate the prevention of parastomal hernia

<b>Submission date</b> 27/11/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 01/02/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/09/2024	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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)

[cipher-study@bristol.ac.uk](mailto:cipher-study@bristol.ac.uk)

## Contact information

### Type(s)

Scientific

### Contact name

Miss Lucy Ellis

### ORCID ID

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

### Contact details

CIPHER Study Coordination Team

University of Bristol

Bristol Trials Centre

1-5 Whiteladies Road

Bristol

United Kingdom

BS8 1NU  
+44 (0)117 455 9216  
Cipher-study@bristol.ac.uk

## 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.

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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?
<a href="#">Protocol article</a>		01/07/2021	09/06/2021	Yes	No
<a href="#">Other publications</a>	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
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol file</a>	version 5.0	05/01/2024	30/04/2024	No	No