UK cohort study to investigate the prevention of parastomal hernia

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

Contact information

Type(s)

Scientific

Contact name

Miss Lucy Ellis

ORCID ID

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Contact details

CIPHER Study Coordination Team University of Bristol Bristol Trials Centre 1-5 Whiteladies Road Bristol United Kingdom

Additional identifiers

Protocol serial number

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.

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

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

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

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

United Kingdom

England

Scotland

Wales

Study participating centre

Royal Devon University Healthcare NHS Foundation Trust

Royal Devon University NHS Ft Barrack Road Exeter United Kingdom

EX2 5DW

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 TrustSalisbury 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

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

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

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

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

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 l added	Peer reviewed?	Patient- facing?
Protocol article	01/07 /2021	09/06 /2021	Yes	No
HRA research summary		28/06 /2023	No	No
What should be included in case report forms? Development and application of novel methods to inform surgical study design: a mixed publications methods case study in parastomal hernia prevention	05/10 /2022	06/10 /2022	Yes	No
Participant information sheet sheet	11/11 /2025	11/11 /2025	No	Yes
Protocol file version 5.0	05/01 /2024	30/04 /2024	No	No