

# How many people suffer from bowel problems following surgery for colorectal cancer, and what treatments are the best for managing these problems?

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<b>Registration date</b> 04/08/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/11/2025	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Colorectal cancer is the third most common cancer worldwide with 14,000 patients in the UK being diagnosed with rectal cancer per year. Over half of those patients will undergo major resectional surgery. Low anterior resection syndrome (LARS) is a consequence of this surgery and describes a constellation of bowel symptoms including urgency, faecal incontinence, stool clustering and incomplete evacuation. It has a significant adverse impact on quality of life (QoL). LARS symptoms are present in up to 75% of the patients in the first year after surgery and may persist in 25%, remaining in up to half of these patients for more than 10 years. There is poor evidence to support the various treatment options currently in use. As disease-free survival is regarded as the most important factor following curative rectal cancer surgery, QoL and potential ways to improve it may be overlooked. Patients are often not aware or not told that bowel function can change significantly following surgery and radiotherapy and may think any adverse effects will be short-term. It is not known when post-operative bowel dysfunction, which may occur after any colonic resection, can be defined as LARS and how the trajectory of LARS changes over time, especially in patients undergoing radiotherapy. An introductory cohort study aims to explore the natural history of LARS, identify predictors of major LARS and screen patients for recruitment to a randomised controlled trial (RCT) that will measure the effectiveness of the new intervention. The aims of the RCT are to evaluate the clinical and cost-effectiveness of transanal irrigation (TAI) or sacral neuromodulation (SNM) versus optimised conservative management (OCM) for people with major LARS.

### Who can participate?

Adult participants aged over 18 years old who have undergone a high or low anterior resection for colorectal cancer in the last 10 years. Participants with major LARS symptoms, defined as a LARS score of 30+, will be eligible to be randomised to the randomised controlled trial element.

### What does the study involve?

Participants who enter the cohort will be asked to complete questionnaires about their quality

of life and bowel symptoms every 3 months for 24 months. Clinical study data will be collected at baseline and then at 12 and 24 months from registration from medical notes.

Participants who enter the RCT will be randomised to receive either TAI, SNM or OCM and will then go on to receive their allocated treatment. Patients will attend the hospital at various times depending on the treatment they are receiving and will also be followed up for trial purposes at 3, 6, 9 and 12 months post-randomisation via a combination of clinic or telephone assessments. At 24 months clinical study data will be collected from medical notes.

What are the possible benefits and risks of participating?

It is possible that taking part in this study means you receive treatment that you may not be offered otherwise, such as TAI. It is hoped that receiving any of the treatments will improve LARS symptoms. However, some treatments may work better for different people, or may not work at all. The information gained from this study will help guide the best approach for the treatment of LARS in the future which will benefit other patients with this condition. All participants will be regularly and closely monitored throughout the study.

There is no additional risk of participating if you are allocated to receive OCM. For participants randomised to receive TAI or SNM there is an additional risk due to potential side effects of these treatments.

Where is the study run from?

The Cardiff and Vale Health Board (UK)

When is the study starting and how long is it expected to run for?

July 2021 to March 2027

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Katie Gordon, K.A.Gordon@leeds.ac.uk (UK)

## Contact information

### Type(s)

Principal investigator

### Contact name

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### ORCID ID

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Public

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## **Additional identifiers**

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
324576

**ClinicalTrials.gov (NCT)**  
Nil known

**Central Portfolio Management System (CPMS)**

# Study information

**Scientific Title**

Pathway of low anterior resection syndrome relief after surgery (POLARiS) trial

**Acronym**

POLARiS

**Study objectives**

Sacral nerve modulation and/or transanal irrigation will reduce the severity of low anterior resection syndrome (LARS) symptoms when compared to an optimised conservative treatment

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 14/06/2023, Health and Care Research Wales (Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; None available; Wales.REC4@wales.nhs.uk), ref: 23/WA/0171

**Study design**

Randomized superiority trial within a cohort study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Low anterior resection syndrome

**Interventions**

POLARiS is a Phase III randomised superiority trial within a cohort (TWiC), with qualitative sub-study and economic evaluation. The aim of the research is to explore the natural history of low anterior resection syndrome (LARS) over time and to compare sacral neuromodulation (SNM) and transanal irrigation (TAI) against optimised conservative management (OCM) for the treatment of major LARS. There are two primary comparisons for the RCT - i) SNM versus OCM and ii) TAI versus OCM. The outcome of interest is the LARS score. Each comparison requires 350 patients. It is estimated that 600 patients in total will be needed to be recruited to the RCT in order to hit these sample size targets.

Patients who have undergone a high or low anterior resection for rectal or sigmoid cancer within the last 10 years will be identified through cancer databases, note screening, outpatient clinics and in-patients workload at NHS hospital sites. Registration and randomisations will be performed centrally using the CTRU automated 24-hour registration/randomisation system,

accessed by sites via the CTRU website. Participants who are eligible for and consent to the RCT will be randomised between two or three treatment options dependent on patient eligibility and availability of treatments at their hospital.

Participants undergoing TAI will attend a one-hour practical education session with a specialist nurse where the device and volume will be decided. Participants randomised to SNM will have a consultation with their local clinician performing the SNM procedure. Participants in the OCM group will have a consultation with a clinical member of the study where appropriate treatments will be instigated.

Participants will be followed up for 24 months and will be reviewed at 3, 6, 9, 12 and 24 months.

Participants will complete questionnaires designed to capture health-related quality of life at baseline and 3 monthly throughout the 24-month follow-up period.

Participants randomised to the RCT are given the opportunity to take part in up to 3 semi-structured interviews to explore the impact of the interventions.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

LARS score measured using the LARS score questionnaire at baseline and every 3 months until 24 months post registration/randomisation

### **Key secondary outcome(s)**

RCT and cohort study:

1. Health-related quality of life and physical, psychological and emotional functioning, is measured using the EORTC QLQ C30, EORTC CR29 and the LARS iCAT questionnaire at baseline and at 3, 6, 12 and 24 months after registration/randomisation
2. Incidence of adverse events related to the trial/trial procedures within 24 months of registration/randomisation, categorised using the CTCAE Grading (plus Clavien-Dindo or ClassIntra classification for adverse events relating to surgery) using medical notes

Secondary outcome measures (RCT only)

1. Generic quality of life measured using EQ-5D-5L, at baseline 3, 6, 12 and 24 months after randomisation
2. Treatment compliance will be measured using medical records
3. Cost-effectiveness will be measured using a health resource use questionnaire at baseline, 3, 6, 12 and 24 months after randomisation and medical records

### **Completion date**

31/03/2028

## **Eligibility**

### **Key inclusion criteria**

General inclusion criteria (cohort):

1. Diagnosis of rectal or sigmoid cancer
2. Low or high anterior resection (colorectal resection with anastomosis to the rectum)
3. Functioning anastomosis

4. Primary surgery less than 10 years before recruitment
5. At least 6 months since reversal of stoma or primary surgery if no stoma created
6. Aged  $\geq 18$  years old
7. Able to provide written informed consent

RCT inclusion criteria - as above plus:

8. Major LARS symptoms within the last 3 months (defined as a LARS score of  $\geq 30$ )
9. Clinically appropriate for randomisation as determined by the treating clinician

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

0

**Key exclusion criteria**

Cohort exclusion criteria:

1. Receiving ongoing chemotherapy, radiotherapy or immunotherapy treatment for cancer
2. Anterior exenteration

RCT exclusion criteria:

3. Receiving ongoing chemotherapy, radiotherapy or immunotherapy treatment for cancer
4. Metastatic disease
5. Inflammatory bowel disease
6. Pregnancy
7. Use of TAI for LARS within 1 month prior to randomisation
8. Not eligible for SNM and not eligible for TAI
9. Anterior exenteration
10. Anastomotic stricture
11. History of anastomotic leak with evidence of ongoing leak/sinus

Plus treatment-specific exclusions:

Exclusion criteria for SNM:

12. History of spinal cord stimulator (added 28/11/2025)
13. Site unable to offer SNM as a treatment
14. Previous SNM

- 15. Specific contraindications to implantation
- 16. Any other contraindications advised by the care team, product manufacturer or distributor
- 17. Margin positive (R1) resection within 24 months prior to randomisation (added 09/10/2024)

RCT exclusion – TAI specific:

Exclusion criteria for TAI:

- 18. Unable to perform TAI
- 19. History of anastomotic leak with evidence of ongoing leak/sinus
- 20. Previous use of TAI for LARS
- 21. Site unable to offer TAI as a treatment
- 22. Any other contraindications advised by the care team, product manufacturer or distributor

**Date of first enrolment**

01/09/2023

**Date of final enrolment**

31/03/2026

## **Locations**

**Countries of recruitment**

United Kingdom

England

Wales

Australia

**Study participating centre**

**Cardiff & Vale University Lhb**

Woodland House

Maes-y-coed Road

Cardiff

Wales

CF14 4HH

**Study participating centre**

**St. James's University Hospital**

Beckett Street

Leeds

England

LS9 7TF

**Study participating centre**

**Aneurin Bevan University Lhb**

Headquarters - St Cadoc's Hospital  
Lodge Road  
Caerleon  
Newport  
Wales  
NP18 3XQ

**Study participating centre****Bolton Royal Hospital**

Minerva Road  
Farnworth  
Bolton  
England  
BL4 0JR

**Study participating centre****Churchill Hospital**

Churchill Hospital  
Old Road  
Headington  
Oxford  
England  
OX3 7LE

**Study participating centre****Addenbrookes**

Addenbrookes Hospital  
Hills Road  
Cambridge  
England  
CB2 0QQ

**Study participating centre****The Royal Victoria Infirmary**

Queen Victoria Road  
Newcastle upon Tyne  
England  
TS1 4LP

**Study participating centre**



**Queens Medical Centre, Nottingham University Hospital**  
Derby Road  
Nottingham  
England  
NG7 2UH

**Study participating centre**  
**St Marks Hospital**  
St. Marks Hospital  
112 St. Marks Road  
Maidenhead  
England  
SL6 6DU

**Study participating centre**  
**University Hospital of North Durham**  
University Hospital of Durham  
Dryburn Hospital  
North Road  
Durham  
England  
DH1 5TW

**Study participating centre**  
**Wythenshawe Hospital**  
Southmoor Road  
Wythenshawe  
Manchester  
England  
M23 9LT

**Study participating centre**  
**Somerset NHS Foundation Trust**  
Trust Management  
Lydeard House  
Musgrove Park Hospital  
Taunton  
England  
TA1 5DA

**Study participating centre**

**Northern General Hospital**

Northern General Hospital NHS Trust  
C Floor, Huntsman Building  
Herries Road  
Sheffield  
England  
S5 7AU

**Study participating centre****Royal London Hospital and Associated Community Services NHS Trust**

The Royal London Hospital  
Whitechapel  
London  
England  
E1 1BB

**Study participating centre****Southampton General Hospital**

Tremona Road  
Southampton  
England  
SO16 6YD

**Study participating centre****Leicester Royal Infirmary**

Infirmary Square  
Leicester  
England  
LE1 5WW

**Study participating centre****James Paget University Hospital**

Lowestoft Road  
Gorleston  
Great Yarmouth  
England  
NR31 6LA

**Study participating centre****Gloucestershire Royal Hospital**

Great Western Road

Gloucester  
England  
GL1 3NN

**Study participating centre**  
**Royal Berkshire Hospital**  
London Road  
Reading  
England  
RG1 5AN

**Study participating centre**  
**Sunderland Royal Hospital**  
Kayll Road  
Sunderland  
England  
SR4 7TP

**Study participating centre**  
**Royal Liverpool University Hospital**  
Prescot Street  
Liverpool  
England  
L7 8XP

## **Sponsor information**

**Organisation**  
Cardiff and Vale University Health Board

**ROR**  
<https://ror.org/0489f6q08>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**

National Institute for Health and Care 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**

Individual participant data (IPD) sharing plan

De-identified individual participant data datasets generated and/or analysed during the current study will be available upon request from the Clinical Trials Research Unit, University of Leeds (contact [CTRU-DataAccess@leeds.ac.uk](mailto:CTRU-DataAccess@leeds.ac.uk) in the first instance). Data will be made available at the end of the trial, i.e. usually when all primary and secondary endpoints have been met and all key analyses are complete. Data will remain available from then on for as long as CTRU retains the data.

**Data Sharing Statement**

CTRU makes data available by a 'controlled access' approach. Data will only be released for legitimate secondary research purposes, where the Chief Investigator, Sponsor and CTRU agree that the proposed use has scientific value and will be carried out to a high standard (in terms of scientific rigour and information governance and security) and that there are resources available to satisfy the request. Data will only be released in line with participants' consent, all applicable laws relating to data protection and confidentiality, and any contractual obligations to which the CTRU is subject. No individual participant data will be released before an appropriate agreement is in place setting out the conditions of release. The agreement will govern data retention, usually stipulating that data recipients must delete their copy of the released data at the end of the planned project.

The CTRU encourages a collaborative approach to data sharing and believes it is best practice for researchers who generated datasets to be involved in subsequent uses of those datasets. Recipients of trial data for secondary research will also receive data dictionaries, copies of key trial documents and any other information required to understand and reuse the released datasets.

The conditions of release for aggregate data may differ from those applying to individual participant data. Requests for aggregate data should also be sent to the above email address to discuss and agree on suitable requirements for release.

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>		03/02/2025	04/02/2025	Yes	No
<a href="#">Study website</a>			28/11/2025	No	No