

Reconstruction after advanced pelvic cancer surgery

Submission date 29/01/2025	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/03/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/04/2025	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Advanced pelvic cancers affecting the bowel, anus, bladder, prostate and reproductive organs are challenging to treat. In the confined pelvic space, cancer easily spreads to nearby organs and muscles, sometimes invading the surrounding anal/genital skin (the perineum). The best chance of cure is radiotherapy, chemotherapy followed by major surgery. This life-changing surgery, called Extended Margin Cancer Surgery (EMCS), removes pelvic organs and the perineum leaving behind a large empty space. This can lead to complications like fluid buildup, infections, and wound breakdown, known as the empty pelvis syndrome. This syndrome affects over half of patients causing long-term health problems, poor quality of life(QoL) and placing a large financial burden on both patients and the NHS. To address these issues, surgeons perform perineal reconstruction using tissue flaps(muscle/skin taken from elsewhere in the body) or animal-derived meshes to fill the empty space and prevent complications. However, little is known about how different reconstruction methods impact QoL, complications, and costs after surgery. The aim of this study is to better understand the impact of different types of perineal reconstruction on QoL, complications and costs within the first 12 months after EMCS.

Who can participate

Patients over the age of 18 years with advanced rectal, anal, gynaecological, bladder, prostate, sarcoma, cancer invading the pelvic floor muscles, needing major surgery to remove the cancer and reconstruct the pelvic floor with either a tissue flap or a mesh.

What does the study involve

This study will recruit 236 patients from 10 NHS centres, ensuring a diverse population. Patients undergoing EMCS and flap or mesh perineal reconstruction will complete QoL questionnaires at recruitment, 3, 6 and 12 months after surgery. We will assess healthcare and patient resource use, financial burden, complications, survival, and cancer recurrence within 12- months after surgery. A selection of patients, ensuring different ages and ethnic representation, will be interviewed to explore the consequences of complications and their impact on QoL and decision-making.

Comparing QoL, complication rates and costs between the two surgical groups will provide valuable information for clinicians and patients, improving communication between patients and their clinical teams, thereby improving shared decisions and reducing regret.

What are the possible benefits and risks of participating?

The study will inform shared decision-making consultations with data captured from patients undergoing these operations as this currently does not exist. No risks for participation are identified.

Where is the study run from?

The study is coordinated from the University Hospital Southampton NHS Foundation Trust and the University of Southampton (UK)

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

December 2021 to January 2028

Who is funding the study?

National Institute for Health Research, Research for Patient Benefit (UK)

Who is the main contact?

1. A/Prof Malcolm West, M.West@soton.ac.uk

2. Prof. Alex Mirnezami

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Mr Malcolm West

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

282783

ClinicalTrials.gov number

NCT05219058

Secondary identifying numbers

CPMS 52006

Study information

Scientific Title

REMACS - understanding the impact of perineal reconstruction after extended margin cancer surgery on longer-term quality of life, morbidity and health economic outcomes - a prospective longitudinal cohort study

Acronym

REMACS

Study objectives

Aim: To determine the effects of extended margin cancer surgery (EMCS), specifically comparing 12-month quality of life (QoL), complications and health economic utilisation between flap and mesh perineal reconstruction groups.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 10/03/2022, North East - Newcastle & North Tyneside 2 Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 22/NE/0032

Study design

Longitudinal observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Quality of life, Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Advanced pelvic cancers

Interventions

Extended margin abdominopelvic cancer operations including abdominoperineal excision with pelvic reconstruction using biological mesh or myocutaneous flaps or primary closure.

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Intervention Type

Procedure/Surgery

Primary outcome measure

Quality of life is measured using the EORTC-QLQ-C30 generic global health at 12 months after surgery

Secondary outcome measures

1. Quality of life is measured using the EORTC-QLQ-C30 generic and cancer-specific module at baseline before surgery and at 3, 6 and 12 months after surgery.
2. Quality of life is measured using the EQ-5D-5L at baseline before surgery and at 3, 6, and 12 months after surgery.
3. Decision-Regret will be measured using the Decision-Regret questionnaire at baseline before surgery and at 3, 6 and 12 months after surgery.
4. Specific quality of life for locally recurrent rectal cancer patients is measured using the LRRC-QoL at baseline before surgery and at 3, 6 and 12 months after surgery
5. Complications will be measured in-hospital and up to 12 months after surgery using the Clavien-Dindo score and Comprehensive Complication Index
6. Comparisons of costs and benefits, with financial toxicity measurements will be measured using the COST questionnaire at baseline before surgery and at 3, 6 and 12 months.
7. Quality-adjusted life years gained will be measured using the EQ-5D-5L at baseline before surgery and at 3, 6 and 12 months after surgery
8. Healthcare resource use data will be measured using unit costs from the National Schedule of NHS Costs will be used to cost resource use over the 12 months after surgery
9. Overall and disease-free survival will be measured at 12 months after surgery

Overall study start date

01/12/2021

Completion date

01/01/2028

Eligibility

Key inclusion criteria

1. Male and female patients aged 18 years and over
2. Locally advanced or locally recurrent cancers arising from the rectum, uterus, ovary, cervix, anus, bladder, prostate, and sarcomas

3. Patients undergoing curative intent EMCS including infralelevator pelvic exenteration(PE) or extralelevator abdomino-perineal excision(ELAPE)
4. Patients undergoing perineal reconstruction with myocutaneous flap or biological mesh

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

236

Key exclusion criteria

1. Unfit, declined or not offered curative intent surgery
2. Inter-sphincteric abdominoperineal resection only
3. Patients undergoing perineal reconstruction with primary skin closure alone
4. Inability or unwillingness to provide informed consent

Date of first enrolment

17/05/2022

Date of final enrolment

01/12/2026

Locations**Countries of recruitment**

England

Scotland

United Kingdom

Wales

Study participating centre

University Hospital Southampton NHS Foundation Trust

Southampton General Hospital

Tremona Road

Southampton

United Kingdom

SO16 6YD

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

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

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

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

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

University Hospitals Dorset NHS Foundation Trust

Management Offices

Poole Hospital

Longfleet Road

Poole

United Kingdom

BH15 2JB

Study participating centre

Yeovil District Hospital NHS Foundation Trust

Higher Kingston

Yeovil

United Kingdom

BA21 4AT

Study participating centre

Swansea Bay University Local Health Board

Tonna Hospital

Tonna Uchaf

Tonna

Neath

United Kingdom

SA11 3LX

Study participating centre

Portsmouth Hospitals University National Health Service Trust

Queen Alexandra Hospital

Southwick Hill Road

Cosham

Portsmouth

United Kingdom

PO6 3LY

Study participating centre

Hampshire Hospitals NHS Foundation Trust

Basingstoke and North Hampshire Hos

Aldermaston Road

Basingstoke

United Kingdom

RG24 9NA

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

Sussex Partnership NHS Foundation Trust

Trust Hq
Swandean
Arundel Road
Worthing
United Kingdom
BN13 3EP

Study participating centre

London North West University Healthcare NHS Trust - Northwick Park Hospital - Oxford Covid19 Trials

Northwick Park Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

Study participating centre

Central Manchester University Hospitals NHS Foundation Trust

Trust Headquarters, Cobbett House
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre

NHS Greater Glasgow and Clyde

J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road Glasgow

Glasgow
United Kingdom
G12 0XH

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

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

Sponsor details
Southampton General Hospital
Tremona Road
Southampton
England
United Kingdom
SO16 6YD

-
sponsor@uhs.nhs.uk

Sponsor type
Hospital/treatment centre

Website
<http://www.uhs.nhs.uk/home.aspx>

ROR
<https://ror.org/0485axj58>

Funder(s)

Funder type
Government

Funder Name

Research for Patient Benefit Programme

Alternative Name(s)

NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Findings will be shared with researchers, healthcare professionals, patients, carers, charities and policymakers through online platforms, media, scientific conferences and journals. PPI and charity partners will lead on dissemination.

Intention to publish date

01/01/2028

Individual participant data (IPD) sharing plan

Fully anonymised data will be stored in a publicly available repository: <https://register.clinicaltrials.gov/>. Quality of life, health economic and surgical outcomes data will be available. Patient-level data will not be made available but can be requested by a formal request to the study principal investigator.

IPD sharing plan summary

Stored in publicly available repository