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Reconstruction after advanced pelvic cancer surgery

Submission date
29/01/2025

Recruitment status
Recruiting

Registration date
26/03/2025

Overall study status
Ongoing

Last Edited
01/04/2025

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
282783

ClinicalTrials.gov (NCT)
NCT05219058

Protocol serial number
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

Study type(s)
Quality of life, Treatment

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.

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.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Quality of life is measured using the EORTC-QLQ-C30 generic global health at 12 months after surgery

Key secondary outcome(s))
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

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 infralevator pelvic exenteration(PE) or extralevator abdomino-perineal excision(ELAPE)
4. Patients undergoing perineal reconstruction with myocutaneous flap or biological mesh

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Scotland

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

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, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Fully anonymised data will be stored in a publicly available repository: https://register.clinicaltrials.gov/. Quality of life, heath 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