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Improving diagnosis and treatment for patients with rectal cancer

Submission date 29/05/2025	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 16/06/2025	**Overall study status** Ongoing	
Last Edited 01/07/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
The purpose of staging is to provide a prognosis of the cancer, namely the risk to the patient's life and the risk of cancer returning.
The cancer stage information from scans guides pre-operative treatment and the type of surgery offered. We are studying whether a new Magnetic Resonance Imaging (MRI) staging method can improve the accuracy of prognosis for patients diagnosed with rectal cancer.

Who can participate?
All adult patients aged 16 years and over who have been diagnosed with rectal cancer

What does the study involve?
We will collect information about your diagnostic tests and treatment. We will ask you to share your experiences by filling in questionnaires at intervals during your patient journey and treatment when you visit the hospital for your doctor's appointments.

What are the possible benefits and risks of participating?
There are no disadvantages to taking part. You will continue to receive standard care, as guided by your local doctors, throughout the trial. We hope that the information from this trial will help us improve the way we classify rectal cancer in future and provide a better understanding of how treatments for rectal cancer impact on patient's lives. This could benefit other patients with the same condition as you in the future. There will be no direct benefit.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
June 2025 to May 2031

Who is funding the study?
NHS England through RM Partners and Pelican Cancer Foundation

Who is the main contact?
Caroline Martin, giclinicaltrials@imperial.ac.uk

Plain English summary under review with external organisation

Study website
https://profginabrown.com/mercury3/

Contact information

Type(s)

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
348532

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 64773

Study information

Scientific Title
Improving the prognostic accuracy of staging rectal cancer using magnetic resonance imaging (MRI) - detected tumour deposits and vascular invasion (mrTDV) instead of tumour nodal metastasis (mrTNM)

Acronym
MERCURY 3

Study objectives
A different staging system that assesses tumour deposits (TDs) and tumour spread into veins (mrTDV) will improve the quality of care of patients diagnosed with rectal cancer compared with the current practice of using tumour nodal metastasis (mrTNM).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/05/2025, East Midlands - Derby Research Ethics Committee (2 Redman Place, London, EC20 1JQ, UK; +44 (0)207 104 8154, +44 (0)207 104 8283, +44 (0)207 104 8146; derby.rec@hra.nhs.uk), ref: 25/EM/0105

Study design
Non-randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Diagnostic

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
Rectal cancer

Interventions
The training of radiologists to implement specialised MRI reporting using the TDV staging system.

Patients in the study will be recruited in two phases: control and intervention.

All eligible patients will be identified in the multidisciplinary meetings and will be registered on the trial. Patients will undergo their normal treatment as determined by their clinical team. For 6 months before training of the radiologists (this is the intervention), scan reports will be captured and compared with histopathology. All scans performed in 2019 will also be captured and compared with histopathology. The results from both these sets of data will be shown to the radiologists as part of their training and discussed with the MDT. Scan reports will then be captured and compared with histopathology for 6 months after the training of the radiologists to compare. Long-term outcomes before and after the intervention will be compared.

In addition, clinical team members will approach patients to consent for quality of life and the shared decision-making process. The patient information sheet explains that we are providing consultant radiologists with the know-how to report MRI scans using a new method and comparing it with the existing method. We explain that this study will test this by comparing how accurately the old vs new method predicts the outcomes for patients.

The clinical team will follow up with the patients for 5 years at 1, 3 and 5 years to report on their long-term outcomes. Consented patients will also be asked to complete a quality of life questionnaire at their routine clinical follow-up appointments. They will not attend clinic for any research-specific reason.

Research staff will capture the number and type of hospital visits and investigations for patients in both the control and intervention phases at one year. This is to compare health resource use between the phases. This data is non-clinical observations about NHS resource use.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Survival for mrTNM and mrTDV before and after the intervention (at 1 and 5 years)

Secondary outcome measures
1. Agreement between radiologists in mrTDV staging vs mrTNM: agreement in prognostic accuracy between radiology and histopathology using TNM versus TDV at 1 and 5 years
2. mrTDV and TNM compared with respective histopathology staging for prognosis: agreement in prognostic accuracy between radiology and histopathology using TNM versus TDV at 1 and 5 years
3. Impact of the introduction of mrTDV staging on MDT decision-making: MDT treatment policies before and after mrTDV intervention at 1 and 5 years

4. Changes in treatment strategy following MRI-TDV staging intervention: treatments given before and after mrTDV intervention at 6 months and 1 year
5. Oncological outcomes for mrTNM versus TDV: disease-free survival (DFS) and local recurrence rates before and after mrTDV intervention at 1 and 5 years
6. Quality of life measured using Qualitative EORTC QLQ-CR29 Questionnaire at 6 months, 1 and 5 years
7. Quality of life measured using Qualitative EORTC QLQ-CR30 Questionnaire at 6 months, 1 and 5 years
8. Bowel function measured using Low Anterior Resection Syndrome (LARS) score at 6 months, 1 and 5 years
9. Patient shared decision making (SDM) measured using SM-Q9 scores at 6 months, 1 and 5 years
10. Validation of an educational programme for radiologists and MDTs to improve MRI reporting with TDV staging: assessment of radiologists' prognostic accuracy and agreement using TNM versus TDV at 6 months and 1 year
12. Comparison of inpatient costs between patients before and after intervention: comparison of relative % histopathological biomarkers screening panels between patients identified by the radiologist on the report before and after intervention at 18 and 36 months
13. Comparison of total cost of outpatient visits between patients based on individual pathways before and after intervention at 18 and 30 months
14. Number of patients without disease and/or without stoma before and after intervention: DFS and stoma-free survival in patients based on individual pathways before and after intervention at 18 and 30 months
15. Assessment of novel and existing histopathological biomarkers to improve prognostic and predictive markers: comparison of relative % histopathological biomarkers screening panels between patients identified by the radiologist on the report before and after intervention at 6, 12, 18 months and 3 and 5 years

Overall study start date
01/06/2025

Completion date
31/05/2031

Eligibility

Key inclusion criteria
1. Have a rectal cancer proven on biopsy or subsequent surgery
2. Sites able to submit anonymised MRI staging scans, pathology and imaging reports for central review
3. Aged 16 years or over

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex

Both

Target number of participants
Planned Sample Size: 438; UK Sample Size: 438

Key exclusion criteria
1. Have irresectable metastatic disease at time of initial staging
2. Undergoing palliative treatment for rectal cancer
3. Have a biopsy-proven rectal malignancy which is not adenocarcinoma
4. Are contraindicated for MRI staging

Date of first enrolment
01/06/2025

Date of final enrolment
31/05/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salisbury District Hospital
Salisbury District Hospital
Odstock Road
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SP2 8BJ

Study participating centre
Southampton
Southampton General Hospital
Tremona Road
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SO16 6YD

Study participating centre
John Radcliffe Hospital
Headley Way
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Study participating centre
Northwick Park Hospital
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HA1 3UJ

Study participating centre
St Marys Hospital
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Warrington
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Study participating centre
Chesterfield Royal Hospital
Chesterfield Road
Calow
Chesterfield
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S44 5BL

Study participating centre
Kings Mill Hospital
Mansfield Road
Sutton-in-ashfield
United Kingdom
NG17 4JL

Study participating centre
The Princess Alexandra Hospital
Hamstel Road
Harlow
United Kingdom
CM20 1QX

Study participating centre
Musgrove Park Hospital (taunton)
Musgrove Park Hospital
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TA1 5DA

Study participating centre
Royal London Hospital
80 Newark Street
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Study participating centre
East Surrey Hospital
Canada Avenue
Redhill
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RH1 5RH

Study participating centre
Worthing Hospital
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United Kingdom
BN11 2DH

Study participating centre
Health Protection Team (NHS Grampian)
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2 Eday Road
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AB15 6RE

Study participating centre
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GU16 7UJ

Study participating centre
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Study participating centre
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Study participating centre
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Sponsor type

University/education

Website
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ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
NHS England

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Prof. Gina Brown (gina.brown@imperial.ac.uk)

IPD sharing plan summary
Available on request