

# Improving diagnosis and treatment for patients with rectal cancer

<b>Submission date</b> 29/05/2025	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/06/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/07/2025	<b>Condition category</b> 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

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

## Contact information

### Type(s)

#### Contact name

Miss Caroline Martin

#### Contact details

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### Type(s)

#### Contact name

Prof Gina Brown

#### ORCID ID

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## Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### Integrated Research Application System (IRAS)

348532

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

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

### Study type(s)

Diagnostic

### 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(s)**

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

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

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

16 years

### **Sex**

All

### **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**

United Kingdom

England

### **Study participating centre**

#### **Salisbury District Hospital**

Salisbury District Hospital

Odstock Road

Salisbury

United Kingdom

SP2 8BJ

### **Study participating centre**

#### **Southampton**

Southampton General Hospital

Tremona Road

Southampton

United Kingdom

SO16 6YD

### **Study participating centre**

#### **John Radcliffe Hospital**

Headley Way

Headington

Oxford

United Kingdom

OX3 9DU

### **Study participating centre**

#### **Northwick Park Hospital**

Watford Road

Harrow

United Kingdom

HA1 3UJ

### **Study participating centre**

**St Marys Hospital**  
Floyd Drive  
Warrington  
United Kingdom  
WA2 8DB

**Study participating centre**  
**Chesterfield Royal Hospital**  
Chesterfield Road  
Calow  
Chesterfield  
United Kingdom  
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  
Taunton  
United Kingdom  
TA1 5DA

**Study participating centre**  
**Royal London Hospital**  
80 Newark Street  
London  
United Kingdom  
E1 2ES

**Study participating centre**

**East Surrey Hospital**

Canada Avenue  
Redhill  
United Kingdom  
RH1 5RH

**Study participating centre**

**Worthing Hospital**

Lyndhurst Road  
Worthing  
United Kingdom  
BN11 2DH

**Study participating centre**

**Health Protection Team (NHS Grampian)**

Summerfield House  
2 Eday Road  
Aberdeen  
United Kingdom  
AB15 6RE

**Study participating centre**

**Frimley Park Hospital**

Frimley  
Camberley  
United Kingdom  
GU16 7UJ

**Study participating centre**

**Southmead Hospital**

Southmead Road  
Westbury-on-trym  
Bristol  
United Kingdom  
BS10 5NB

**Study participating centre**

**York District Hospital**  
Wigginton Road  
York  
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YO31 8HE

**Study participating centre**  
**Basingstoke and North Hampshire Hospital**  
Aldermaston Road  
Basingstoke  
United Kingdom  
RG24 9NA

## Sponsor information

**Organisation**  
Imperial College London

**ROR**  
<https://ror.org/041kmwe10>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
NHS England

## Results and Publications

### 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](mailto:gina.brown@imperial.ac.uk))

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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[Study website](#)

Study website

11/11/2025

11/11/2025

No

Yes