ISRCTN53688111 https://doi.org/10.1186/ISRCTN53688111

# Assessing the use of artificial intelligence in rectal magnetic resonance imaging

**Submission date**
26/11/2024

**Recruitment status**
Recruiting

**Registration date**
29/11/2024

**Overall study status**
Ongoing

**Last Edited**
07/11/2025

**Condition category**
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
This study aims to assess an artificial intelligence (AI) technique, more specifically deep learning reconstruction (DLR), that can make MR images clearer and more detailed, whilst also being able to complete the scan in a much shorter time. This AI technique has already been established at numerous NHS trusts and is a CE-marked product, however, requires validation in MRI rectum scans at St George's Hospital. MRI scans of the rectum are only performed for patients who are diagnosed with rectal cancer. These scans have been proven to select patients for the right treatment. Patients with a more advanced disease need tumour shrinkage for successful surgery. Therefore all patients with rectal cancer will have an MRI scan at diagnosis and patients who need additional treatment before surgery have another MRI scan to show that this has worked and help plan their surgery. As a result, all patients having a rectal MRI scan irrespective of where on their cancer pathway they are (diagnosis or post-downstaging) will be invited to take part.

Who can participate?
Staff in the Medical Physics and Engineering group, plus adult patients that have been referred to St George's Hospital General Radiology MRI department for an MRI pelvis study and able to withstand up to an additional 15 minutes in the MRI scanner will be considered for participation in this study.

What does the study involve?
The study involves optimising an MRI protocol based on the existing clinical MRI rectum protocol but with DLR techniques enabled to facilitate a reduction in acquisition times. This will be carried out on healthy volunteers until image quality is demonstrated to be equivalent or improved compared to the existing clinical protocol. Once achieved, this will be validated on patient participants. Validation will also involve assessing image quality using Likert scores, as well as, by acquiring biomarker measurements.

What are the possible benefits and risks of participating?
For healthy volunteers from the Medical Physics and Clinical Engineering Group, the benefits

include a better understanding of the patient experience in MRI. The risk to healthy volunteers is that there is an incidental finding (a discovery made by chance during an imaging test that is not related to the reason for the test).

For patient participants, the benefits include additional imaging that will provide additional information to the radiologist reading their images which may result in improved care. The risk to the patients includes additional time spent inside the MRI scanner that could increase the effects of claustrophobia or anxiety.

Where is the study run from?
St George's Hospital's General Radiology MRI Department.

When is the study starting and how long is it expected to run for?
September 2024 to July 2026.

Who is funding the study?
This study is unfunded with any resources used in this study volunteered by St George’s Hospital’s General Radiology MRI department & Medical Physics and Clinical Engineering Department.

Who is the main contact?
Zach Pang (Study Coordinator), zach.pang@stgeorges.nhs.uk

# Contact information

### Type(s)
Principal investigator

### Contact name
Dr Anita Wale

### ORCID ID
https://orcid.org/0000-0002-5203-4670

### Contact details
St George’s Hospital, Blackshaw Rd
London
United Kingdom
SW17 0QT
+44 (0)208 725 6368
anita.wale@stgeorges.nhs.uk

### Type(s)
Public, Scientific

### Contact name
Mr Zach Pang

### Contact details
Blackshaw Rd
London
United Kingdom

SW17 0QT
+44 (0)2082666244
zach.pang@stgeorges.nhs.uk

# Additional identifiers

### Integrated Research Application System (IRAS)
345225

### Protocol serial number
JRES: 2024.0133

# Study information

### Scientific Title
Quantitative assessment of image quality in rectal cancer MR images when using artificial intelligence reconstruction techniques

### Study objectives
AI reconstruction techniques can be successfully implemented into the MRI rectal protocol, providing improved image quality and/or reduced acquisition times improving patient outcomes and staff workload.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
approved 16/12/2024, Cambridge South REC (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 (0)207 104 8084; cambridgesouth.rec@hra.nhs.uk), ref: 24/EE/0247

### Study design
Single-centre blinded observational study

### Primary study design
Observational

### Study type(s)
Diagnostic, Other

### Health condition(s) or problem(s) studied
Validation of deep learning reconstruction techniques used in clinical MRI rectum studies.

### Interventions
This is a single-centre blinded observational study to demonstrate Deep Learning Reconstruction-enabled rectum MRI protocols are equivalent or superior to the pre-existing clinical protocol.

Healthy volunteers will be imaged using the existing MRI rectum protocol with imaging repeated using the Deep Learning Reconstruction technique aimed at reducing acquisition times and demonstrating equivalent or improved image quality to the existing clinical protocol.

Images will be assessed using a Likert scoring system and will only be trialled on patients if /when the median Likert scores of the Deep Learning Reconstruction enabled protocol is >= the median Likert scores of the existing clinical protocol.

Once demonstrated, the same Likert scoring plus biomarker measurements will be used to validate the sequence by demonstrating equivalency on patients with rectal cancer by imaging with the existing and Deep Learning Reconstruction enabled sequences.

### Intervention Type
Other

### Primary outcome(s)
Following a reduction in the acquisition time, equivalent image quality is achieved demonstrated by median Likert scores of the DLR enabled protocol >= median Likert scores of the clinical protocol as assessed by a blinded radiologist. Assessment is performed only once, following the MRI acquisitions.

Likert scoring consists of a five-point system that assesses: signal to noise ratio; rectal wall sharpness/conspicuity; overall image quality; and bowel motion.

### Key secondary outcome(s))
1. Agreement between the clinically relevant measurements of rectal tumours on DLR enabled versus clinical scans using biomarker measurements following the MRI acquisition at one timepoint
2. Potential benefits of using DLR-enabled protocols, including shortened acquisition times and improved imaged quality measured using key performance indicators, such as increased patient throughput, over the course of the study

### Completion date
30/07/2026

## Eligibility

### Key inclusion criteria
Staff:
Staff in the Medical Physics and Engineering group

Patients:
1. Adult patients who have been referred to St George’s Hospital General Radiology MRI department for an MRI pelvis study
2. Able to withstand up to an additional 15 minutes in the MRI scanner

### Participant type(s)
Employee, Healthy volunteer, Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 years

### Upper age limit
100 years

### Sex
All

### Key exclusion criteria
1. Any volunteer who is not an adult
2. Pregnancy
3. Any patient who cannot give informed written consent
4. Cannot complete a screening questionnaire
5. Has not been referred for an MRI pelvis scan for a rectum study at St George’s Hospital General Radiology MRI department as an outpatient
6. Is an at-risk patient
7. Non-English speakers

### Date of first enrolment
16/12/2024

### Date of final enrolment
30/05/2026

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**St George's University Hospitals NHS Foundation Trust**
Blackshaw Rd
London
United Kingdom
SW17 0QT

## Sponsor information

### Organisation
St George's Hospital

### ROR

https://ror.org/02507sy82

# Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
St George's University Hospitals NHS Foundation Trust

### Alternative Name(s)

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Other non-profit organizations

### Location
United Kingdom

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to patient confidentiality.

### IPD sharing plan summary
Not expected to be made available

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version 6.0 | 28/11/2024 | 29/11/2024 | No | Yes |
| Participant information sheet | version 5.0 | 28/11/2024 | 29/11/2024 | No | Yes |
| Participant information sheet | version 4.0 | 28/11/2024 | 29/11/2024 | No | Yes |
| Participant information sheet | version 4.0 | 28/11/2024 | 29/11/2024 | No | Yes |
| Protocol file | version 7.0 | 28/11/2024 | 29/11/2024 | No | No |