

# Planning using MRI for anal and rectal cancer radiotherapy treatment

<b>Submission date</b> 27/01/2020	<b>Recruitment status</b> Suspended	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/03/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/05/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Almost half of cancer patients undergo radiotherapy as part of their treatment. Currently radiotherapy treatment planning involves using a CT scan to maximise radiation to the cancer whilst minimising radiation dose to healthy tissue. For many cancers the extent of the tumour is seen much better on Magnetic Resonance Imaging (MRI). This study will assess whether MRI can replace CT for radiotherapy planning for ano-rectal cancers.

### Who can participate?

Adult patients (> 18 years) undergoing radiotherapy at Leeds Teaching Hospitals NHS Trust or the Northern Centre for Cancer Care (NHS) for anal and rectal cancers.

### What does the study involve?

Patients who are already receiving radiotherapy as part of their treatment undergoing radiotherapy in Leeds Cancer Centre will be invited to participate in an imaging study where an additional MRI scan is obtained after informed consent have been taken. This study will have no impact on the participant's treatment. The MRI scan will be used to compare the new method of treatment planning with the current method used routinely in patient care.

### What are the possible benefits and risks of participating?

There are no direct benefits to taking part, however taking part will help patients in the future. There are some limited risks of taking part, associated with having an MRI scan. All risks will be clearly explained in the information sheets for the study.

### Where is the study run from?

Leeds Teaching Hospitals NHS Trust (UK)

The researchers are collaborating with the Northern Centre for Cancer Care (NCCC) based at Freeman Hospital Newcastle-upon-Tyne, the Calvary Mater Newcastle Hospital (Australia), The Australian e-Health Research Centre (Royal Brisbane and Women's Hospital), a consortium of UK institutions supported by Cancer Research UK Centres Network Accelerator Award Grant (A21993) (ART-NET) and two medical companies: Spectronics Medical AB (Sweden) and Philips Healthcare (The Netherlands), to help develop this way of planning treatments. NCCC will

participate in recruitment, the other collaborators will participate in the analysis of the anonymised data.

When is the study starting and how long is it expected to run for?  
August 2018 to April 2021

Who is funding the study?  
National Institute for Health Research (NIHR) (UK)

Who is the main contact?  
David Bird  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr David Bird

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**  
243334

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
CPMS 39102, IRAS 243334

## Study information

**Scientific Title**  
MANTA-RAY: MRI-only treAtmeNT planning for Anal and Rectal cAncer radiotherapY

**Acronym**

MANTA-RAY

**Study objectives**

MR-only treatment planning is technically accurate, clinically implementable and has potential benefit for external beam radiotherapy treatments for ano-rectal cancer patients.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 01/08/2018, London - Surrey Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 1048058; nrescommittee.secoast-surrey@nhs.net), ref:19/LO/1298

**Study design**

Interventional non-randomized study

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**Study setting(s)**

Hospital

**Study type(s)**

Diagnostic

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Colorectal Cancer

**Interventions**

This is technical process which will be carried out to assess whether MRI scans can be used to plan radiotherapy treatments, instead of the current standard of using CT scans, in patients with anal and rectal cancers who are due to undergo radiotherapy. This study will be investigating the clinical implementability of the whole treatment pathway for anal and rectal cancer patients including it's potential benefit.

A cohort of Leeds Cancer Centre and Northern Centre for Cancer Care patients due to undergo radiotherapy will have an additional, research only, MRI scan acquired. These patients will be identified by their clinical team or the research team as suitable when attending radiotherapy outpatient clinics. Suitable patients will be provided with a patient information sheet about the study and at the next visit to the radiotherapy clinic written informed consent will be obtained by the clinical or research team. The additional research MRI scan will be scheduled to coincide

with radiotherapy appointments so that patients do not routinely need to come for an additional visit. All patient data will then be anonymised before analysis.

No IV contrast will be given with the MRI scans.

Anonymised patient MRI and CT scans from the Leeds Cancer Center and Northern Centre for Cancer Care patients will be shared under Information Governance authorisation to develop the technical process.

The researchers will not be collecting nor sharing any clinical information on patients.

### **Intervention Type**

Device

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

MRI

### **Primary outcome measure**

Phase 1 - Quantification of radiotherapy treatment plan measured by dosimetric difference between CT and synthetic-CT (generated from MRI data) datasets

Phase 2 - Quantification of differences in target volumes and reduction in dose to organs at risk for CT vs MRI-only based radiotherapy treatment plans

Phase 3 - Quantification of systematic and random errors attributable to use of MRI or sCT data vs CT data for patient treatment position registration using CBCT

### **Secondary outcome measures**

None

### **Overall study start date**

01/05/2018

### **Completion date**

01/05/2021

## **Eligibility**

### **Key inclusion criteria**

1. Adult patients (>18 years) undergoing radiotherapy at Leeds Teaching Hospitals NHS Trust or the Northern Centre for Cancer Care (NHS) for anal and rectal cancers
2. Ability to give written informed consent

### **Participant type(s)**

Patient

### **Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 60; UK Sample Size: 60

**Key exclusion criteria**

Standard clinical contra-indications to MRI scanning (claustrophobia, pacemaker).

**Date of first enrolment**

28/09/2018

**Date of final enrolment**

01/12/2020

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**St James's University Hospital**

Leeds Teaching Hospitals NHS Trust

Beckett Street

Leeds

United Kingdom

LS9 7TF

**Sponsor information****Organisation**

Leeds Teaching Hospitals NHS Trust

**Sponsor details**

St. James's University Hospital

Beckett Street

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LS9 7TF

+44 (0)113 2060469  
anne.gowing@nhs.net

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.leedsth.nhs.uk/home/>

**ROR**

<https://ror.org/00v4dac24>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

NIHR Academy; Grant Codes: ICA-CDRF-2017-03-005

**Funder Name**

National Institute for Health Research (NIHR) (UK)

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**

01/05/2022

## 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 and trust data-sharing policy as agreed in the study REC/HRA approval.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Interim results article</a>	Multicentre, deep learning, synthetic-CT generation for ano-rectal MR-only radiotherapy treatment planning	01/03/2021	19/05/2023	Yes	No
<a href="#">Interim results article</a>	Patient position verification in magnetic-resonance imaging only radiotherapy of anal and rectal cancers	01/07/2021	19/05/2023	Yes	No
<a href="#">Interim results article</a>	The benefit of MR-only radiotherapy treatment planning for anal and rectal cancers: A planning study	22/10/2021	19/05/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No