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Planning using MRI for anal and rectal cancer radiotherapy treatment

Submission date
27/01/2020

Recruitment status
Suspended

Registration date
12/03/2020

Overall study status
Completed

Last Edited
19/05/2023

Condition category
Cancer

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

Plain English Summary
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 hypothesis
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 Commitee (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

Condition
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 Cencer 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

Overall study end date
01/05/2021

Eligibility

Participant 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

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

Recruitment start date
28/09/2018

Recruitment end date
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
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LS9 7TF

Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust

Sponsor details
St. James's University Hospital
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+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 confidentially 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?
Interim results article	Multicentre, deep learning, synthetic-CT generation for ano-rectal MR-only radiotherapy treatment planning	01/03/2021	19/05/2023	Yes	No
Interim results article	Patient position verification in magnetic-resonance imaging only radiotherapy of anal and rectal cancers	01/07/2021	19/05/2023	Yes	No
Interim results article	The benefit of MR-only radiotherapy treatment planning for anal and rectal cancers: A planning study	22/10/2021	19/05/2023	Yes	No
HRA research summary			28/06/2023	No	No