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Streamlining Staging of Colorectal cancer with Whole Body MRI

Submission date	Recruitment status	[X] Prospectively registered
24/07/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/07/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/12/2019	Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-mri-scan-diagnose-bowel-cancer-streamline-c

Study website
http://www.ctc.ucl.ac.uk/TrialDetails.aspx?TrialID=64

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Comprehensive staging of newly diagnosed colorectal cancer: prospective multi-centre comparison of whole body Magnetic Resonance Imaging with standard diagnostic imaging pathways

Acronym
Streamline C

Study objectives
To evaluate whether early whole body magnetic resonance Imaging (WB-MRI) increases per patient sensitivity for metastasis in colorectal cancer compared to standard NICE-approved diagnostic pathways.

More details can be found at http://www.hta.ac.uk/project/2804.asp

Ethics approval required
Old ethics approval format

Ethics approval(s)
Camden and Islington Research Ethics Committee, 20 August 2012, ref: 12/LO/1176

Study design
Multicentre comparison

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please contact ctc.streamlineC@ucl.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied
Colorectal cancer

Interventions
5. There are no treatment arms, every patient will receive a whole body MRI as part of the trial which takes about an hour. Aside from attending for the WB-MRI scan, patients shouldnt have to attend for any extra visits. All patients will be asked to complete quality of life forms (EQ-5D) at 0, 3, 6 and 9 months post staging. As part of the health economics portion of the trial, all patients will also be asked to complete patient diaries which will collect information about visits to the GP and hospital and about other medical tests and treatment for a year post staging. As part of the health psychology portion of the trial, 25 patients will take part in an interview (30 minutes) and 75 patients will be given questionnaires complete about their experience of staging at 0, 1, 3, 6, 9, and 12 months post staging. Follow-up CRFs will be completed for a year post-staging but there are no trial specific visits, this data is collected for the health economic portion of trial.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Per patient sensitivity for metastasis detection by whole body MRI (WB-MRI) compared to standard staging pathways in newly diagnosed colorectal cancer

Secondary outcome measures
1. The time and test number taken to reach, and the nature of, the first major treatment decision based on WB-MRI in comparison to standard staging pathways.
2. Diagnostic accuracy of WB-MRI and conventional staging pathways for local tumour staging and detection of metastasis in comparison to an expert derived consensus reference standard.
3. Lifetime incremental cost and cost-effectiveness of staging using WB-MRI compared to standard diagnostic pathways.
4. Patient experience of staging using WB-MRI in comparison to standard diagnostic pathways and priorities placed by patients on differing attributes related to competing staging pathways.
5. Inter-observer variability in WB-MRI analysis and affect of diagnostic confidence on staging accuracy.
6. Diagnostic accuracy of limited T1 and diffusion weighted sequences compared to full multi-sequence WB-MRI protocols.

Overall study start date
01/10/2012

Completion date
01/01/2019

Eligibility

Key inclusion criteria
1. Adult patients (18 or over) with histologically proven or suspected colorectal cancer referred for staging.
2. Suspicion of colorectal cancer defined as: Presence of a mass highly suspicious for colorectal cancer on endoscopy, barium enema, CT colonography or other imaging which triggers staging

investigations.
3. Patient must have given written informed consent and be willing to comply with the protocol intervention and follow up.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
322

Total final enrolment
370

Key exclusion criteria
1. Any psychiatric or other disorder likely to impact on informed consent
2. Evidence of severe or uncontrolled systemic disease which make it undesirable for the patient to participate in the trial
3. Pregnancy
4. Contraindications to MRI (e.g. cardiac pacemaker, severe claustrophobia, inability to lie flat)
5. Polyp cancer (because metastatic disease in these patients is vanishingly rare)

Date of first enrolment
01/10/2012

Date of final enrolment
01/04/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
University College London (UK)

Sponsor details
Cancer Research UK & UCL Cancer Trials Centre
90 Tottenham Court Road
London
England
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W1T 4TJ

Sponsor type
University/education

Website
http://www.ctc.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Not defined

Funder Name
NIHR Helath Technology Assessment Programme - HTA (UK) ref: 10/68/01

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	result	01/07/2019	14/05/2019	Yes	No
Results article	comparative results against ISRCTN50436483	01/12/2019	20/12/2019	Yes	No