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Improving the prediction of metastatic disease in primary colorectal cancer

Submission date 10/08/2011	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/08/2011	**Overall study status** Completed	
Last Edited 16/04/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
We are carrying out a study to see if we can improve the imaging of colorectal cancer using a type of Computed Tomography (CT) scan known as perfusion CT. This type of scan can measure blood supply to tumours and we hope to use this information to improve our understanding of how tumours may behave and so future treatment.

Who can participate?
Men and women, aged 18 years or over, with suspected or proven colorectal cancer.

What does the study involve?
Participants will undergo an additional CT scan, which lasts approximately 2 minutes. This is carried out at the same time as the usual CT scan that participants would normally have. During the scan a dye will be administered through a needle in the participant's arm. Also, a bowel relaxant called buscopan will be given by injection to achieve a better quality scan image. Participants will continue to attend clinic visits for the first three years following the additional scan.

What are the possible benefits and risks of participating?
There may be no immediate benefit to those taking part. However the information we get from the study will help us to improve scan imaging of future patients and to possibly assess future cancer treatment. The main risk associated with the study is the increased radiation dose that comes with receiving an additional CT scan. The dye that is administered during the scan may cause mild side effects including nausea and vomiting, or a rash. An allergic reaction occurs rarely and may require drug treatment. Buscopan commonly causes a dry mouth. Other side effects are rare and include fast beating heart, shortness of breath and skin reactions.

Where is the study run from?
Bradford Royal Infirmary
Guy;s and St Thomas; Hospital, London
Western General, Edinburgh
University Hospital of North Staffordshire
Churchill Hospital, Oxford

Queen Alexandra Hospital, Portsmouth
Royal Cornwall Hospital, Truro
Northern General Hospital, Sheffield
Southampton General
Ninewells Hospital, Dundee
York Hospital
St James' University Hospital, Leeds

When is the study starting and how long is it expected to run for?
The study began recruiting in November 2011, and participants will be enrolled for 12-15 months. Recruitment will end in early 2013.

Who is funding the study?
National Institute for Health Research - Health Technology Assessment Programme

Who is the main contact?
PROSPECT study team, phs.prospect@phs.scot

Contact information

Type(s)
Scientific

Contact name
Dr Joanna Dunlop

Contact details
Scottish Clinical Trials Research Unit (SCTRU)
Public Health Scotland (PHS)
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United Kingdom
EH12 9EB
None provided
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9423

Study information

Scientific Title
Improving the prediction of metastatic disease in primary colorectal cancer: prospective multicentre evaluation of a prognostic model of conventional predictive variables and novel variables derived from perfusion computed tomography

Acronym
PROSPECT

Study objectives
To improve the prediction of metastatic disease in patients with colorectal cancer by developing a prognostic model based on disease free survival, that is superior to current practice, via prospective evaluation of both conventional predictive variables and novel variables derived from perfusion computed tomography (CT).

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC, 20/01/2011, ref: 10/H0713/84

Study design
Non-randomised, interventional

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

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
1. Perfusion computed tomography (CT) sequence
2. An additional perfusion CT sequence during the standard contrast-enhanced staging CT
3. Follow Up Length: 36 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. To improve the prediction of metastatic disease in patients with colorectal cancer by developing a prognostic model based on disease-free survival
2. Measured at 3 and 5 years for each individual patient

Secondary outcome measures
No secondary outcome measures

Overall study start date
31/01/2011

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Patients with suspected or proven (via optical colonoscopy and biopsy) colorectal cancer attending for pre-operative staging CT
2. Suspicion of colorectal cancer defined as:
2.1. Presence of a mass highly suspicious for colorectal cancer on barium enema, CT colonography or other imaging
2.2. Large bowel obstruction
2.3. Elevated serum CEA
3. Ability to provide informed written consent
4. Aged 18 years or over
5. Male or female participants

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 370; UK Sample Size: 370

Total final enrolment
326

Key exclusion criteria

1. Inability to provide informed written consent
2. Pregnancy
3. Renal impairment defined as serum creatinine >1150mmol/L
4. Previous iodinated contrast allergy
5. Inability to cannulate
6. Inability to lie flat
7. Weight greater than 200 kg (maximum weight capacity of CT scanner is 200 kg)

Date of first enrolment
01/11/2011

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
ISD Cancer Clinical Trials Team
Edinburgh
United Kingdom
EH12 9EB

Sponsor information

Organisation
King's College London

Sponsor details
The Strand
London
England
United Kingdom
WC2R 3LS

Sponsor type
Hospital/treatment centre

Website
http://www.kcl.ac.uk

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
NIHR - Health Technology Assessment Programme (HTA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
30/04/2024

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		05/06/2024	11/06/2024	Yes	No
Results article		16/04/2025	16/04/2025	Yes	No