ISRCTN05107772 https://doi.org/10.1186/ISRCTN05107772

Quicksilver: a study to assess the safety of a new MRI approach to pre-operatively stage rectal cancer and guide treatment

Submission date
03/07/2014

Recruitment status
No longer recruiting

Registration date
23/07/2014

Overall study status
Completed

Last Edited
12/04/2019

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
All patients diagnosed with rectal cancer have an MRI to determine whether the rectal cancer is early or advanced. Patients with early cancer proceed directly to surgery and based on tests done on the rectal cancer after surgery may require chemotherapy and/or radiation. Patients with advanced rectal cancer have chemotherapy and radiation before surgery and chemotherapy after surgery. The advantage of having chemotherapy and radiation before surgery is that it decreases the risk of the rectal cancer coming back. However, the disadvantage of having chemotherapy and radiation before surgery is that it does not improve overall survival (i.e. chance of cure) and leads to slightly poorer bowel and sexual function than when surgery is performed alone. Therefore, the results of the MRI are very important because they determine whether the rectal cancer is early or advanced and whether or not chemotherapy and radiation will be required before surgery.
Currently, the standard criteria used on MRI to determine whether the rectal cancer is early or locally advanced are depth of tumour invasion into the bowel wall (T-category) and involvement of lymph nodes (N-category). Recently, two studies from Europe have used new MRI criteria using the predicted resection margin (rim of normal tissue surrounding the tumour) to determine whether the rectal cancer is early or locally advanced. These studies showed that when using this new MRI criteria, more rectal cancers were classified as early and, therefore, fewer patients required chemotherapy and radiation before surgery. These studies showed that even though fewer patients received chemotherapy and radiation before surgery, the risk of the rectal cancer coming back was low. Since these studies were done in different countries, the purpose of this study is to assess whether the new MRI criteria is safe to use in Canada.

Who can participate?
Patients aged 18 years or older with rectal cancer.

What does the study involve?
Participants will receive the exact same tests and surgery that they would receive if they were not participating in this study. However, instead of using the current selection criteria to make a treatment recommendation about having chemotherapy and radiation before surgery, a less

strict selection criteria will be used to decide whether or not to recommend chemotherapy and radiation. This means that by participating in the study, participants will be less likely to receive chemotherapy and radiation than if they were not participating in the study. The surgical procedure they receive will be the same regardless of whether or not they participate in this study, as will their care following surgery. The portion of the rectum (including the tumour) that has been removed will be examined in the usual way by the pathologist.

What are the possible benefits and risks of participating?
The potential benefit of not undergoing chemotherapy and radiation before surgery is that the length of treatment will be about 2-3 months shorter and participants will have better bowel and sexual function with surgery alone than if they have chemotherapy and radiation before surgery. Although two studies have shown that using the new MRI criteria is safe and has the same local recurrence rate as standard MRI criteria (which is around 7.5%), we are not 100% certain of this. Therefore, while we do not think that the local recurrence rate will be more than 7.5% using the new MRI criteria, there is a chance that the local recurrence rate could be as high as 15%, which is two times higher than our standard approach.

Where is the study run from?
Fifteen hospitals from across Canada will be participating in this study.

When is the study starting and how long is it expected to run for?
The study will start in September 2014 and end in September 2016.

Who is funding the study?
Mount Sinai Hospital (Canada).

Who is the main contact?
Dr Erin Kennedy

Contact information

Type(s)
Scientific

Contact name
Dr Erin Kennedy

Contact details
Mount Sinai Hospital
600 University Avenue
Toronto
Canada
M5G 1X5

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A Phase II prospective cohort study to assess the safety of a new MRI approach to pre-operatively stage rectal cancer and guide treatment

Study objectives
It is expected that the results of this study will show that this new approach to the selection of rectal cancer patients for pre-operative chemoradiotherapy using MRI to predict the circumferential resection margin will be safe.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Mount Sinai Hospital Research Ethics Board, 08/01/2014, ref: 13-0147A

Study design
Phase II prospective cohort study

Primary study design
Interventional

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
N/A

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

Interventions
Participants (i.e., rectal cancer patients) in this study will receive the exact same tests and surgery that they would receive if they were not participating in this study. However, instead of using the current or more strict selection criteria to make a treatment recommendation about pre-operative chemoradiotherapy (preCRT), a more refined or less strict selection criteria will be used to decide whether or not to recommend preCRT. This means that by participating in the study, participants will be less likely to receive preCRT than if they were not participating in the study. The surgical procedure they receive will be the same regardless of whether or not they

participate in this study, as will their care following surgery. The portion of the rectum (including the tumour) that has been removed will be examined in the usual way by the pathologist.

Added 12/09/2017: The MRI criteria for identifying "good prognosis tumors" has been amended and now studies are collecting additional 2-year outcomes on the participants. The 2-year outcomes collected include the following: (i) local recurrence, (ii) distant metastasis, (iii) disease free survival and (iv) overall survival.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
The primary outcome for the study will be the safety of this new MRI approach in terms of positive circumferential resection margin (CRM) in the pathological specimen. The positive CRM rate is a well-established and accepted surrogate measure of local recurrence and the new MRI criteria will be considered safe if a positive CRM rate of less than 5% is achieved.

Secondary outcome measures
N/A

Overall study start date
01/09/2014

Completion date
01/06/2018

Eligibility

Key inclusion criteria
1. Diagnosis of rectal cancer (0-15 cm) from the anal verge on endoscopy and/or proximal extent of tumour at or below the sacral promontory on CT or MRI
2. 18 years or older
3. Able to provide written consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

A total of 75 patients from all participating centres across Canada

Total final enrolment
82

Key exclusion criteria
1. Planned abdomino-perineal resection (APR) based on pre-treatment assessment
2. Planned local excision based on pre-treatment assessment
3. Suspicious extramesorectal lymph nodes on MRI
4. Unable to undergo MRI due to claustrophobia, metal fragments, implanted metal devices or contrast allergy
5. Metastatic disease (including extramesorectal lymph nodes, carcinomatosis, liver, lung)
6. Pregnancy
7. Inflammatory bowel disease
8. Previous pelvic radiation
9. More than one primary tumour

Date of first enrolment
01/09/2014

Date of final enrolment
01/09/2016

Locations

Countries of recruitment
Canada

Study participating centre
Mount Sinai Hospital
Toronto
Canada
M5G 1X5

Sponsor information

Organisation
Mount Sinai Hospital (Canada)

Sponsor details
Toronto General Hospital, NCSB LC-412
585 University Avenue
Toronto
Canada
M5G N2N

Sponsor type
Hospital/treatment centre

Website
http://www.mountsinai.on.ca/

ROR
https://ror.org/05deks119

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Mount Sinai Hospital (Canada), University Health Network Academic Medical Organization Innovation Fund

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	results	01/07/2019	12/04/2019	Yes	No