Validation of ultrahigh field (7 Tesla) MRI with whole mount pathology in rectal cancer

Published: 28-08-2017
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Pathologic validation of tumour volume, location, and microscopic extension on 7 Tesla MR images using whole mount histopathology.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON48569

Source
ToetsingOnline

Brief title
7MaRC

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
rectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,MLDS (Maag Lever Darm Stichting)

Intervention

Keyword: 7 Tesla MRI, rectal cancer

Outcome measures

Primary outcome

The accuracy of 7 Tesla MRI in determining the residual tumour volume, location, and extension after neoadjuvant radiotherapy. Location is determined by comparison of the center of the tumour on 7T images and in whole mount pathology. The tumour extension is defined as the distance between the outline of the tumour in pathology and the tumour outline on imaging.

Secondary outcome

Define the most optimal 7T sequences in determining tumour volume, validated with pathology;.

If available, a comparison of tumour volume as determined on 7T and 3T images will be made.

Study description

Background summary

Radical surgery following chemoradiation is effective in achieving disease control in patients with locally advanced stage rectal cancer, but associated with substantial morbidity. After chemoradiation, 15-20% of patients don*t show residual tumour cells at postoperative histological examination. In these pathological complete responders, surgery might be safely omitted. However, preoperative identification of patients with a pathological complete response (pCR) is challenging due to misinterpretation of radiation induced changes as tumour and missing of microscopic residual tumour. Use of ultra-high field 7 Tesla MRI may improve the diagnostic accuracy of identifying a complete response following chemoradiation.

Study objective

Pathologic validation of tumour volume, location, and microscopic extension on 7 Tesla MR images using whole mount histopathology.

Study design

A pathology validation study of MR imaging in 10 patients with rectal cancer, nested within a prospective colorectal cancer cohort (PLCRC). Patients undergo 7 Tesla MRI prior to surgery. Rectal specimens are subjected to whole mount pathologic examination, in which the entire specimen is examined, allowing for accurate spatial correlation with MR images.

Study burden and risks

The patient risk and burden associated with this study is minimal. Study participation possibly requires one extra hospital visit to undergo 7 Tesla MRI prior to surgery. After rectal cancer surgery, the surgical specimen including the tumour will be imaged ex vivo using 7 Tesla MRI. Because of the extensive histopathological procedure (whole mount examination), the pathological diagnosis may be delayed by several days. This will not interfere with adjuvant treatment. There is no individual benefit.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Informed consent for PLCRC;
* Informed consent for the use of clinical data
* Informed consent for future studies within PLCRC;
* Eligible for neoadjuvant radiotherapy;
* Eligible for rectal surgery by Total Mesorectal Excision (either Low Anterior Resection, Abdominoperineal Resection or Hartmann resection).

Exclusion criteria

* Patients with distant metastasis requiring surgery between chemoradiation and rectal surgery;
* MRI contraindications according to the MR safety protocol of the imaging division of the UMC Utrecht.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-03-2018
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	28-08-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-01-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	17-07-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-05-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL60928.041.17