USPIO- enhanced High Field MRI for restaging lymph node status in rectal cancer: an explorative study

Published: 08-08-2016 Last updated: 15-04-2024

To validate the use of 3 and 7 Tesla nano-MRI in restaging locally advanced rectal cancer by node-to-node matching of the results of nano-MRI with pathology as the gold standard.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metastases
Study type	Observational invasive

Summary

ID

NL-OMON45911

Source ToetsingOnline

Brief title USPIO- enhanced High Field MRI for restaging rectal cancer

Condition

Metastases

Synonym lymph node metastases

Research involving Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: lymph node metastasis, lymphography, rectal cancer, USPIO

Outcome measures

Primary outcome

Sensitivity and specificity of 3T and 7T MRI scans with ferumoxtran-10

enhancement for lymph node metastasis detection after chemoradiotherapy in

locally advanced rectal cancer patients. We will make a subdivision into small

(<5mm) and large nodes (*5mm).

Secondary outcome

Comparing the sensitivity and specificity of 3T and 7T

Study description

Background summary

Locally advanced rectal cancer is treated by neoadjuvant chemoradiotherapy followed by a total mesorectal excision. Total mesorectal excision (TME) is associated with a large impact on guality of life and patients might end up with a permanent colostoma. The decision towards surgical treatment is made on the basis of a restaging MRI after chemotherapy. Because of the impact on the quality of life of a TME, the current paradigm is shifting towards organ preserving treatments. One of the key factors in determining an adequate treatment plan is knowing how much the disease has progressed into the regional lymph nodes. Determining this lymph node status however, is a challenge, and the current techniques used in the restaging MRI have a sensitivity of approximately 60% for detecting these lymph nodes. One of the methods to improve upon this sensitivity is the use of lymph node specific contrast agents, such as Ferumoxtran-10: an ultrasmall superparamagnetic iron oxide (USPIO) particle that has proven to be a valuable contrast agent for detecting lymph node metastases using magnetic resonance imaging (MRI) in various types of cancer (also called nano-MRI). We would like to perform a node to node validation of nano-MRI in rectal cancer after neoadjuvant chemoradiotherapy, to evaluate its performance at the time of a restaging MRI. With this, we can improve the sensitivity for detection of small lymph node metastases when restaging rectal cancer. As affected lymph nodes in

the mesorectum can be really small, the nano-MRI scan is also performed on a 7 Tesla MRI scanner for the highest possible sensitivityto detect small lymph node metastases. Nano-MRI results will be validated with pathology. The total mesorectal excision, which includes the mesorectal lymph nodes enables an accurate node-to-node comparison between MRI and pathology to validate our nano-MRI results.

Study objective

To validate the use of 3 and 7 Tesla nano-MRI in restaging locally advanced rectal cancer by node-to-node matching of the results of nano-MRI with pathology as the gold standard.

Study design

Observational study

Study burden and risks

Except for the discomfort of lying in two separate MRI scanners for about 1 hour, MRI offers no risks for patients without pre-assessed contra-indications (e.g. metallic implants). The contrast agent ferumoxtran-10 can cause a contrast reaction during and shortly after administration. Therefore this administration is performed within the hospital under supervision of qualified personnel.

Contacts

Public Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 10 Nijmegen 6500 HB NL **Scientific** Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 10 Nijmegen 6500 HB NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

General criteria:

- Age > 18 years;Specific Inclusion criteria:;- Patients with recently histologically proven rectal cancer, who are:;o Planned to undergo neoadjuvant radiotherapy 50.4 Gy with concomitant chemotherapy consisting of capecitabin 825-1000 mg/m2 and/or oxaliplatin 85 mg/m².;and;o Planned to undergo a total mesorectal excision.

Exclusion criteria

General exclusion criteria:;- Abdominal circumference > 120cm

- Pregnancy;- Karnofsky score <= 70;- Contraindications for 3T MRI:

o Epilepsy

o Inability to provide informed consent

o Metal implants that are not compatible with 3 Tesla MRI;- Contraindications to USPIO based contrast agents:

o prior allergic reaction to ferumoxtran-10 or any other iron preparation

o prior allergic reaction contributed to dextran or other polysaccharide, in any preparation o prior allergic reaction to contrast media of any type

o hereditary hemochromatosis, thalassemia, sickle cell anemia;;- Contraindications to bisacodyl or butylscopolamine:

o cardiac arrhythmia,

o myasthenia gravis,

o urinary retention,

o gastrointestinal stenoses,

o kidney failure

o glaucoma, ;- Inflammatory diseases of the abdomen (such as Crohn*s disease);- Previous oncological related abdominal and/or pelvic surgery or radiotherapy

Study design

Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	06-09-2017
Enrollment:	20
Туре:	Actual

Medical products/devices used

Generic name:	7 Tesla MRI
Registration:	No
Product type:	Medicine
Brand name:	ferumoxtran-10
Generic name:	ferumoxtran-10

Ethics review

Approved WMO Date:	08-08-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-09-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-04-2017

5 - USPIO- enhanced High Field MRI for restaging lymph node status in rectal cancer: ... 29-05-2025

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-11-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2016-002588-32-NL
ССМО	NL58295.091.16