MR Imaging of Lymphadenopathy in Rectal Cancer using the MR Agent Vasovist

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Primary objective• To validate the potential of Vasovist®-enhanced MRI for accurate prediction of nodal status in patients with primary rectal cancer using histopathological examination after surgery as the SOR.Secondary objectives• To compare the...

Ethical review	Approved WMO
Status	Suspended
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON31454

Source
ToetsingOnline

Brief title
Vasovist in Rectal Cancer

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
bowel cancer, rectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Bayer Schering Pharma,Schering

Intervention

Keyword: Imaging, MRI, Rectal Cancer, Vasovist

Outcome measures

Primary outcome

Sensitivity, specificity, NPV and PPV of Vasovist®-enhanced MRI for detection

lymph nodes with tumor infiltration (node-by node analysis)

Secondary outcome

na

Study description

Background summary

Lymphadenopathy is a risk factor for local recurrence in rectal cancer. If one can predict this risk factor preoperatively, together with other risk factors for local recurrence, such as narrow circumferential resection margin, one is able to develop tailored treatment for rectal cancer patiënt, preventing under- as well as overtreatment. In this pilot study we would like to investigate whether nodal status in rectal cancer can be predicted preoperatively using Vasovist®-enhanced MRI.

Study objective

Primary objective
• To validate the potential of Vasovist®-enhanced MRI for accurate prediction of nodal status in patients with primary rectal cancer using histopathological examination after surgery as the SOR.

Secondary objectives
• To compare the value of Vasovist®-enhanced MRI for prediction of nodal status with unenhanced MRI
• To compare the total number of positive and negative lymph nodes in Vasovist®-enhanced MRI with the total number of positive and negative lymph nodes in unenhanced MR images
• To compare the potential of Vasovist®-enhanced MRI for detection of extra-mesorectal lymph nodes with unenhanced MR imaging
• To assess image quality of Vasovist®-enhanced MRI in comparison to unenhanced

MRI
• To assess the confidence level of diagnosis of Vasovist®-enhanced MRI in comparison to unenhanced MRI
• Safety of Vasovist® application (occurrence of adverse events)

Study design

Patients with primary rectal cancer will undergo MRI imaging of the pelvis without contrast agent and after IV application of Vasovist®. The MR images will be interpreted by experienced radiologists. Image findings of Vasovist®-enhanced MRI (amongst others number of positive and negative lymph nodes, tumor stage) will be compared with histopathology as the SOR and unenhanced MRI as the comparator.

Study burden and risks

Patients will undergo MRI scan as a routine pretreatment investigation. In this study, Vasovist® is administered during the MRI scan through intravenous injection. Afterwards, postcontrast images will be made, therefore total scan duration will be approximately 15 minutes longer. Furthermore, there is a small risk of adverse events caused by the contrastagent.

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

Biopsy-proven rectal cancer
Age: at least 18 years
Surgery for rectal cancer planned within 60 days after Vasovist-enhanced MRI
Willing and able to undergo all study procedures
Written informed consent

Exclusion criteria

Age < 18 years
Pregnant and/or nursing women
Contra-indication for MRI
Previous severe allergic reaction to MR-contrast agent
Allergy to any of the ingredients of VAsovist
History of previous malignancy

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	12-07-2008

Enrollment:	90
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Vasovist
Generic name:	gadofosveset trisodium
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	28-06-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	06-09-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-12-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2007-001860-56-NL
CCMO	NL17960.068.07