Early detection of hepatic metastasis in follow-up high-risk colorectal carcinoma

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20752

Source
NTR

Brief title
The EDAM study

Health condition

Early detection of hepatic metastasis in follow-up high-risk colorectal carcinoma

Sponsors and support

Primary sponsor: Noordwest Ziekenhuisgroep Wilhelminalaan 12 1815 JD Alkmaar
Source(s) of monetary or material Support: Board of Directors, Noordwest Ziekenhuisgroep
Department Imaging, NWZ Alkmaar
Department Radiology, NWZ Alkmaar

Intervention

Outcome measures

Primary outcome

1. To investigate if follow-up of asymptomatic patients with high-risk colorectal carcinoma with reduced protocol MRI liver instead of US will affect the time to diagnosis recurrent liver

metastasis (LM-2) in months starting from postoperative control (=randomization); TRLM.

Secondary outcome

To investigate if follow-up of asymptomatic patients with high-risk colorectal carcinoma with reduced protocol MRI liver instead of US will affect:
2. Time to diagnosis of first liver metastasis (LM-1) in months starting from postoperative control (=randomization); TFLM.
3. Time between first postoperative control and diagnosis of first liver metastasis (LM-1); liver metastasis free survival 1 (LMFS-1).
4. Time between diagnosis LM-1 and diagnosis LM-2 in months; liver metastasis free survival 2 (LMFS-2).
5. The proportion of patients who are potentially eligible for curative therapy when detecting LM-1.
6. 5 year survival.
7. Anxiety and quality of life.
8. To compare sensitivity and specificity for detection of liver metastasis between US and reduced MRI liver protocol.

Study description

Background summary

Rationale: Each year, in the Netherlands 15,500 people develop colorectal carcinoma and about 5,100 patients die of this condition, particularly due to the development of metastases. Approximately 50-60% of patients will develop liver metastases. The risk of developing liver metastases is highest in colorectal carcinoma patients with positive locoregional lymph nodes, the so-called high-risk colorectal carcinoma patients (pN1 / N2). About 40-50% of these patients will develop metastases within 3 years. When patients develop liver only metastases, local treatment with curative intent is preferred. After curative resection of the liver metastases up to 75% of the patients develop recurrent liver metastases5 and the 5-year survival is 40-50%. However, we assume the earlier liver metastases are diagnosed, the higher the chance a curative resection can be performed. To detect liver metastases as early as possible, all patients with colorectal carcinoma are followed for at least 5 years. Six, 12, 24 and 36 months after surgery an ultrasound of the patients liver is performed. Furthermore every 6 months the tumor marker CEA in blood is determined. The sensitivity of ultrasound for the detection of liver metastases is 57%[2]. The sensitivity of MRI for the detection of liver metastases is 88%[3]. However a MRI of the liver is costly and time consuming compared to ultrasound. The estimation is that a shortened MR protocol of the liver (saves money and time, compared to an extensive protocol) increases the sensitivity for the detection of colorectal liver metastases, compared to ultrasound. This means that liver metastases are detected earlier. We assume the earlier liver metastases are diagnosed, the chances of curation will increase. We hypothesize that use of the shortened MRI protocol instead of ultrasound in the postoperative surveillance will reduce the risk of and extend the time to

possible recurrent liver metastasis.
Objective: The primary objective of this study is to investigate if follow-up of asymptomatic patients with high-risk colorectal carcinoma with reduced protocol MRI liver instead of US will affect the time to diagnosis recurrent liver metastasis (LM-2) in months starting from postoperative control (=randomization); TRLM.
Secondary objectives are to investigate if follow-up of asymptomatic patients with high-risk colorectal carcinoma with reduced protocol MRI liver instead of US will affect TFLM, LMFS-1, LMFS-2, the proportion of patients who are potentially eligible for curative therapy, 5-year survival, anxiety and quality of life and to compare sensitivity and specificity between US and the shortened MRI liver protocol.
Study design: This study is designed as a randomized, single blinded, parallel group, controlled trial.
Study population: Patients between 18-80 years who manage the Dutch language (given the questionnaires) with pT1-4 N1/2 M0 colorectal carcinoma, WHO performance score 0 or 1, after giving informed consent, will be included in the study.
Intervention: Patients in the control group will undergo US at regular intervals (6,12,24 and 36 months after surgery) as part of a common care. Besides these US's the intervention group will also undergo a shortened MRI liver protocol at these intervals. This is necessary to obtain a sound comparison of sensitivity and specificity between US and the shortened MRI protocol.
Main study parameters/endpoints: 5 year survival.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: In the intervention group besides regular US an MRI of the liver will be performed. The potential risk outweighs the likely benefit.

Study objective

We hypothesize that use of the shortened MRI protocol instead of ultrasound in the postoperative surveillance will reduce the risk of and extend the time to possible recurrent liver metastasis.

Study design

Baseline, 6 months, 12 months, 24 months, 36 months and 60 months.

Intervention

Patients in the control group will undergo US at regular intervals (6,12,24 and 36 months after surgery) as part of a common care. Besides these US's the intervention group will also undergo a shortened MRI liver protocol at these intervals. This is necessary to obtain a sound comparison of sensitivity and specificity between US and the shortened MRI protocol.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, patients must meet all of the following criteria:
- Patients 18-80 years with pT1-4 N1/2 M0 colorectal carcinoma
- WHO performance score 0 or 1
- Being able to give informed consent and to manage the Dutch language (given the questionnaires)

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Claustrophobia
- MRI incompatible devices
- Age > 80 years
- Not mastering the Dutch language (given the questionnaires)
- Pregnancy and lactation

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2020
Enrollment:	174
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	20-04-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48841
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8773
CCMO	NL66499.029.18
OMON	NL-OMON48841

Study results