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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON48841

Source
ToetsingOnline

Brief title
EDAM study

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Metastases

Synonym
liver metastasis

Research involving
Human

Sponsors and support

Primary sponsor: Noordwest Ziekenhuisgroep
Source(s) of monetary or material Support: NWZ

Intervention

Keyword: follow-up high-risk colorectal carcinoma, hepatic metastasis, MRI, ultrasound

Outcome measures

Primary outcome

Primary study parameter/endpoint

1. Time to diagnosis recurrent liver metastasis (LM-2) in months starting from postoperative control (=randomization);TRLM.

Secondary outcome

Secondary study parameters/endpoints

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 (HADS-A (anxiety score), SF-36 (QOL), QLQ-C30).

8. Sensitivity and specificity of both US as reduced MRI liver protocol for

detection of liver metastasis.

Study description

Background summary

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 lymphnodes, 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 resection of the liver metastases, 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. The hypothesis is that earlier detection of a first liver metastasis (LM 1) can reduce the risk to and extend time to develop/diagnose (possibly) recurrent liver metastasis (LM 2).

Study objective

1. 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:

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 design

This study is designed as randomized, single blinded, parallel group controlled trial.

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 comparison of sensitivity and specificity between US and the shortened MRI protocol.

Study burden and risks

In the intervention group besides regular US an MRI of the liver will be performed. The potential risk outweighs the likely 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

High risk colorectal carcinoma

Exclusion criteria

- 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:	Open (masking not used)
Control:	Active

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-06-2020
Enrollment:	174
Type:	Actual

Ethics review

Approved WMO

Date:	15-10-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20752
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL66499.029.18
OMON	NL-OMON20752