Follow-up after surgery for colorectal liver metastasis: the prospective multicentre FUTURE-mets study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON52640

Source
ToetsingOnline

Brief title
Follow-up after surgery for liver metastasis: the FUTURE-mets study

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
Colon cancer metastasized to the liver, colorectal liver metastases

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: KWF (grant application number 10706); Stichting Coolsingel

Intervention

Keyword: Colorectal liver metastasis, Follow-up, Prospective cohort study, Quality of life

Outcome measures

Primary outcome

The primary outcome of this trial is the quality of life. The effect of follow-up on health related quality of life will be assessed by the validated European Organisation for Research and Treatment of Cancer core quality of life questionnaire (EORTC QLQ-C30).

Secondary outcome

In addition to evaluating the quality of life using a retrospective questionnaire, ecological momentary assessment will also be performed. The momentary quality of life is considered one of the secondary endpoints and will be evaluated every 10 days for the entire duration of the study by requesting patients to complete the Life Evaluation Index (LEI) from the larger Gallup Healthways Well-Being Index (GHWBI) on their smartphone (or computer if desired).

The other secondary outcomes are anxiety (measured by the State-Trait Anxiety Inventory: six-item short-form (STAI-6)), fear of cancer recurrence (measured by the cancer-worry subscale of the assessment of survivor concerns (ASC-CW)), survival, and cost-effectiveness. Cost-effectiveness will be evaluated by calculating the incremental cost-effectiveness (C/E) ratios, using the EQ-5D-5L questionnaire as a utility measure and by assessing the intramural costs directly associated with the follow-up after resection of CRLM(assessed by

review of medical records) and extramural costs (assessed by a selection of relevant questions from the Medical Consumption Questionnaire (iMCQ) form the institute of Medical Technology Assessment).

All of the retrospective questionnaires, with the exception of the ASC-CW, will be completed at baseline and every 6 months thereafter until the end of the study (3 years after inclusion). The ASC-CW scale will be completed once at 12 months following inclusion and in case of no disease recurrence. This is due to the concern that the nature of the questions of the ASC-CW might directly affect the measurement of itself and/or other questionnaires when completed frequently. The ecological momentary assessment of momentary quality of life will be performed for the entire duration of the study.

Since up to 70% of recurrences after curative treatment of CRLM present within 2 years, the expected effect of the intervention is greatest in this time-window. Therefore, analyses of the primary and secondary endpoints will be performed 18 months after inclusion of the last patient (roughly 2 years after curative treatment of CRLM) and after completion of the study (3 years after inclusion of the last patient). The study will be seen as successful if quality of life measured at 18 months is non-inferior compared to reference values.

Study description

Background summary

To date no evidence-based surveillance protocol after resection of colorectal liver metastasis (CRLM) has been developed, mostly due to the lack of prospectively gathered data. The traditional follow-up approach in most hospitals consists of regular clinical evaluation, carcinoembryonic antigen (CEA) monitoring and thoracoabdominal CT-scans. However, current literature indicates that follow-up could mainly be based on CEA monitoring and that other diagnostic modalities have little additional value, with regards to survival outcomes.

As frequent multimodality surveillance does not seem to result in better survival outcomes, improvement of follow-up should focus on optimizing patients* quality of life, rather than survival. A patient-controlled follow-up scheme, mainly consisting of CEA level monitoring at home, might be feasible and beneficial from both a patient and societal perspective. In view of the increasing importance of value based healthcare and patient reported outcomes, evaluation of such a surveillance programme is needed.

The current prospective study aims to evaluate a patient-controlled surveillance strategy. We hypothesize that a patient-controlled follow-up results in improved quality of life outcomes after treatment of CRLM.

Study objective

The primary objective of this trial is to evaluate quality of life outcomes in patients with CRLM during a patient-controlled follow-up approach. Secondary objectives are to evaluate anxiety, fear of cancer recurrence, survival, and the cost-effectiveness of this follow-up approach.

Study design

A multicentre prospective cohort study.

Intervention

Patients will enrol in a patient-controlled surveillance strategy. In this follow-up approach blood sampling will be performed at home by the patients themselves using a self-administered blood-sampling kit. Serum CEA monitoring will be performed every 3 months during the first 2 years of follow-up after inclusion and every 6 months thereafter. Further clinical evaluation with use of subsequent medical imaging at the discretion of the specialist will be performed in case of symptoms, CEA levels above 5 µg/L or a two-fold increase in serum CEA compared to the first postoperative CEA, or two consecutive increases in serum CEA. Patients will have one planned in hospital evaluation with medical imaging (CT and/or MRI) 1 year (12 months) after inclusion. In

case of normal CEA values, patients decide themselves whether in hospital evaluation is desired.

Study burden and risks

We hypothesize that a patient-controlled follow-up at home improves quality of life outcomes and reduces anxiety and fear of cancer recurrence. These hypotheses were substantiated by way of systematic patient-interviews. We also expect the patient-controlled approach to achieve an equal or greater cost-effectiveness. No differences in survival outcomes are expected based on our extensive review of currently available literature.

This study will provide valuable insights in the questions currently surrounding follow-up, mainly whether current follow-up practices based on frequent hospital visitations and medical imaging can be replaced by a more modern, patient centred follow-up schedule performed mainly, if desired, at home. Therefore, our aim is to identify an optimal way of monitoring patients after resection of CRLM. An individualized surveillance approach fits well with the current era of value based healthcare and patient reported outcomes. The results of this trial will be used to create evidence based guidelines for long-term surveillance of these patients.

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

- Patients with CRLM treated with curative intent
- Age >= 18 years
- ECOG performance status <= 2
- Histologically confirmed and previously resected primary colorectal carcinoma
- Disease-free at three to six months after CRLM treatment (assessed by medical imaging)
- Disease-free at three to six months after treatment for colorectal metastases and a history of CRLM (assessed by medical imaging)

Exclusion criteria

- Metastatic extrahepatic disease (EHD) precluding curative treatment of CRLM
- Patients with confirmed hereditary CRC
- Patients enrolled in other studies that require strict adherence to any specific follow-up practice with regular imaging - yearly or more frequent - of the abdomen and/or thorax
- Patients with comorbidity that requires imaging of the abdomen and/or thorax every year or more frequent
- Inability to complete the questionnaires due to illiteracy and/or insufficient proficiency of the Dutch language

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-07-2019
Enrollment:	138
Type:	Actual

Ethics review

Approved WMO Date:	20-12-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-01-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-07-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-12-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-11-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-11-2024

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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: 26930
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	NTR7278
CCMO	NL66210.078.18