Follow-up after surgery for liver metastases: the FUTURE-mets study

No registrations found.

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

Summary

ID

NL-OMON26930

Source
NTR

Brief title
FUTURE-mets

Health condition

Colorectal cancer
Colorectal liver metastases
Quality of life
Shared decision making
Follow-up
Cost-effectiveness

Sponsors and support

Primary sponsor: Prof. Dr. C. Verhoef, Erasmus MC Cancer Institute
Source(s) of monetary or material Support: Funding for the study has been provided by the Dutch Cancer Society (KWF) under grant application number 10706.

Intervention

Outcome measures

Primary outcome

The primary outcome of this study is the quality of life. The effect of follow-up on quality of life will be assessed by the validated European Organisation for Research and Treatment of Cancer core quality of life questionnaire – Emotional Functioning Scale (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 surgical treatment 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 enrolment). The ASC-CW scale will be completed once at 12 months following enrolment 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. In case of disease recurrence patients are no longer requested to complete the iMCQ questionnaire as patients are no longer undergoing study follow-up. If disease recurrence is found before 12 months after enrolment, subjects are no longer requested to complete the ASC-CW at 12 months. 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 2-4. 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 enrolment of the last patient). The study will be seen as successful if quality of life measured at 18 months after enrolment proves non-inferior compared to reference values, all the while achieving an equal or greater cost-effectiveness compared to previous standard of care.

Study description

Background summary

To date no evidence-based surveillance protocol after surgical treatment of colorectal liver

metastasis (CRLM) has been developed, mostly due to the lack of prospectively gathered data. The current standard of care follow-up approach in most hospitals consists of regular clinical evaluation, carcinoembryonic antigen (CEA) monitoring and medical imaging (thoracoabdominal CT-scans and/or MRI). 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, especially in light of the worldwide COVID-19 pandemic. In view of the increasing importance of value based healthcare, patient reported outcomes, and mandatory national social distancing measures, 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 after surgical treatment of CRLM is non-inferior in quality of life outcomes compared to reference values for recurrent/metastatic CRC patients.

Study design: A multicentre prospective study.

Study objective

A patient-controlled follow-up after surgery for colorectal liver metastasis mainly consisting of CEA assessments at home improves quality of life outcomes and reduces anxiety and fear of cancer recurrence when compared to the current standard of care follow-up, while maintaining an equal or greater cost-effectiveness and with no expected differences in overall or cancer-specific survival outcomes.

Study design

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) or when patients leave the study due to disease recurrence. The ASC-CW scale will be completed once at 12 months following inclusion and in case of no disease recurrence.
In case of disease recurrence patients are requested to complete the QLQ-C30, STAI-6 and EQ-5D-5L at time of disease recurrence and once six-months thereafter. If disease recurrence is found before 12 months after inclusion, subjects are no longer requested to complete the ASC-CW. The ecological momentary assessment of momentary quality of life will be performed for the entire duration of the study, regardless of disease recurrence.

Intervention

In order to determine non-inferiority in quality of life 138 patients need to be included in the study.
Follow-up will be performed for up to 3 years after enrolment. Patients will enroll in a patient-controlled surveillance strategy. In this study 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 enrolment and every 6 months thereafter. Further clinical and diagnostic evaluation will be performed in case of symptoms, CEA levels above 5 µg/L or a greater than 25% increase of CEA levels compared to the prior measurement. Patients will have one planned in hospital evaluation with medical imaging (CT and/or MRI) 1 year after enrolment. In case of normal CEA values, patients decide whether clinical evaluation will be performed.

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Eligibility criteria

Inclusion criteria

- Patients with CRLM treated with curative intent
- Age ≥ 18 years
- ECOG performance status ≤ 2 (Appendix A)
- Histologically confirmed and previously resected primary colorectal carcinoma
- Disease-free at three to six months after CRLM treatment (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:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2019
Enrollment:	138
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	28-05-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52640
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7080
NTR-old	NTR7278
CCMO	NL66210.078.18
OMON	NL-OMON52640

Study results