Patient-empowered Remote Oncology: the Prospective, Multicentre Implementation Study - the PROMISE

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Primary Objective: To further develop and evaluate a personalised patient-centred surveillance programme including a feedback platform for patients after curative treatment for CRC in terms of health-related quality of life (HRQoL).The goal is for...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON56503

Source
ToetsingOnline

Brief title
PROMISE

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures

Synonym
cancer in the colon and/or rectum, colorectal carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Koningin Wilhelmina

Fonds;LifeSignals Inc.,Lifesignals Inc.

Intervention

Keyword: Colorectal carcinoma, e-Health, Follow-up, Patient-empowerment

Outcome measures

Primary outcome

Primary Objectives: To further develop and evaluate a personalised patient-centred surveillance programme including a feedback platform for patients after curative treatment for CRC in terms of health-related quality of life (HRQoL). Significantly decreasing the number of in-hospital appointments.

The first primary outcome for this surveillance program is non-inferiority to standard of care follow-up at 36 months, in terms of quality of life. The quality of life in patients will be assessed with the EQ-5D-5L questionnaire and compared to the median EQ-5D-5L VAS score, 62.05 points, of patients in standard of care follow-up.

Secondly, the primary outcome consists of significantly decreasing the number of in-hospital appointments, by relocating this follow-up care to the home setting. At 36 months postoperatively patients in standard of care follow-up will have had 10 appointments in the outpatient clinic. For the patients included in the PROMISE study, a significant decrease of the number of in-hospital appointments is defined as having had a median number of in-hospital appointments at 36 months follow-up of 7 or less.

Secondary outcome

In this study, secondary endpoints will be:

- Use of the LifeSignals biosensor:

o A goal of larger than 40% of patients correctly applying the sensor and

generating data from it

o A goal of a score of 4/5 or 5/5 for at least 33% on every

patient-satisfaction question

- Need for safety loop around advice regarding CEA results

- Anxiety: measured by The State-Trait Anxiety Inventory: Six-Item Short-form

(STAI-6)

- Fear of cancer recurrence: measured by the Assessment of Survivor Concerns -

Cancer Worry subscale (ASC-CW)

- Survival: Both overall and cancer-specific, calculated from the date of

surgical resection to the date of death or last follow-up

- Cost-effectiveness

- Patient and healthcare provider user satisfaction with e-Health app platform:

A two item questionnaire (Appendix D)

Study description

Background summary

With the increase of ageing populations and incidence of cancer worldwide, the accessibility of cancer care is under high pressure. The higher number of patients requiring cancer care will receive that care from a decreasing number of health care workers: the double aging phenomenon. Cancer care itself has developed enormously and fortunately the number of cancer care survivors will continue to increase. Fundamental action needs to take place to adapt healthcare systems to be future proof.

Despite this seemingly rational notion, multiple large randomised controlled trials and systematic reviews have failed to show any (cancer-specific) survival benefit of intensive postoperative surveillance compared to a minimalistic approach. The need for intensive imaging is lacking, reducing the need for in-hospital scans: only 1 follow-up CT is recommended in the current Dutch CRC guideline. Furthermore, frequent hospital visits have a significant impact on patient anxiety, as follow-up visits evoke distress around the time of visit. This begs the question whether an (intensive) in-hospital postoperative surveillance strategy is still warranted from both a patient well-being as well as a societal healthcare cost perspective.

An optimal follow-up programme for CRC patients, but in fact all cancer patients, should be patient-centred and adaptive to patients* needs. Smart measurement technologies such as smart eHealth, biosensors, and minimal invasive blood measurement techniques for tumour markers are essential in allowing adequate monitoring of patients* well-being in the comfort of their own homes without the need to travel. Future cancer care should focus on achieving a personalised patient-empowered approach to surveillance, in which the PROMISE will take initiative.

Study objective

Primary Objective: To further develop and evaluate a personalised patient-centred surveillance programme including a feedback platform for patients after curative treatment for CRC in terms of health-related quality of life (HRQoL).

The goal is for this surveillance program to be non-inferior to standard of care follow-up at 36 months, in terms of quality of life. The quality of life in patients will be assessed with the EQ-5D-5L questionnaire and compared the quality of life score of patients in standard of care follow-up. A second primary endpoint is to to relocate part of the in-hospital follow-up care to the home-setting. The effect of the PROMISE study on the number of in-hospital appointments, will be assessed at 36 months postoperatively.

Secondary Objective(s):
The secondary objectives of this study are:
- To evaluate use of the biosensor
o Feasibility of biosensor use
o Patient satisfaction with biosensor use
- To evaluate need for the safety loop for CEA feedback
- To evaluate the fear of cancer
- To evaluate anxiety
- To compare overall and cancer-specific survival
- To measure patient satisfaction
- To determine and compare the cost-effectiveness of follow-up

Study design

The PROMISE study is a multi-centre prospective regional implementation study of a personalised patient-centred surveillance program including a feedback platform for patients after curative treatment for CRC. Follow-up will be carried out for up to five years after surgery.

Follow-up will be performed in accordance with the current Dutch national guidelines. Blood sampling will take place at home, while the actual CEA measurements will be centralised in Erasmus Medical Centre (EMC). The interpretation of the results will be carried out by the treating physician at the participating centre, where the initial treatment was performed. Blood sampling is planned every six months during the first two years after surgery and every twelve months thereafter. One year after surgery medical imaging (according to national guidelines) and clinical evaluation will be scheduled. Further in hospital evaluation will only be performed in case of abnormal CEA values or if specifically desired by the patient. Subsequent use of medical imaging is used according to national guidelines and local practices. The frequency of CEA sampling is according to current Dutch national guidelines and can be increased when clinically indicated (e.g. CEA increase or symptoms). The biosensor will be sent to a patient*s home every three months during the first two years after inclusion and every six months thereafter. Patients will wear the biosensor for a period of five days or as long as the biosensor stays attached to their chest. At coinciding time intervals the TAP-II device will be send to a patient*s home in one package with the biosensor. During these surveillance moments patients will also be asked to fill in questionnaires through the application. The application *Digizorg* will have an important role in assisting patients in the home setting. The app will give patients feedback on CEA, offering personalised advice to help take appropriate action when needed. Furthermore, the app will make insight in personal medical information and making appointments easier.

Study burden and risks

Bringing this type of follow-up to a patient*s home could decrease stress and anxiety, increase health-related quality of life (HRQoL) and patient satisfaction. It also gives a much broader view of a patient*s wellbeing than a relatively brief contact between a patient and a health care provider in a busy outpatient clinic. Hence, the primary research question is to evaluate patient-empowerment when patients receive contextual feedback about their quality of life and the tumour marker CEA.

The feedback system provides tailored advice when the CEA tumour marker deviates from predefined thresholds. This feedback system will suggest to seek contact with the treating cancer specialist. This platform will be completely compliant to standard care according to current national guidelines about

tumour marker assessment and imaging. In case patients do not follow advice given, a safety loop is activated.

As earlier described, the potential risks are very low.

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

- Age >= 21 years
- Histologically confirmed colorectal adenocarcinoma without distant metastasis and treated with curative intent surgical resection less than 6 months ago
- Scheduled or currently undergoing postoperative surveillance according to national guidelines
- Written informed consent by the patient

- Access to a smartphone

Exclusion criteria

- Patients with a severely complicated postoperative course, needing in hospital follow-up longer than 6 months postoperatively
- 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 or other malignancy that requires imaging of the abdomen and/or thorax every year or more frequent
- Patients with active implantable devices - e.g. pacemaker or implantable defibrillator
- Inability to complete the questionnaires due to illiteracy and/or insufficient proficiency of the Dutch language

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-07-2024
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	26-02-2024
Application type:	First submission

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

No registrations found.

In other registers

Register	ID
CCMO	NL84788.078.23