Advanced Geriatric Evaluation in predicting long term health related quality of life in elderly patients with ColoRectal Cancer

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1. To determine the predictive value of frailty characteristics for loss of HRQL in elderly patients with non-metastatic CRC.2. To develop an AGE-CRC score, a prediction model for loss of HRQL in elderly patients with CRC based on comorbidity, risk...

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

Summary

ID

NL-OMON46313

Source
ToetsingOnline

Brief title
AGE-CRC

Condition

- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
fragile, frailty, vulnerability

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: St. Antonius Ziekenhuis en VIOZ(stichting Vrienden Intergrale Oncologische Zorg)

Intervention

Keyword: Colorectal cancer, Geriatric assessment, Preoperative assessment

Outcome measures

Primary outcome

Primary endpoint is a loss of HRQL * 10 points(EORTC-QLQ-C30) at 12 months

after CRC diagnosis.

Secondary outcome

Secondary endpoints are: HRQL after 3 and 6 months (EORTC-QLQ-C30/CR29),

disability free survival after 3, 6 and 12 months (EQ-5D), postoperative

complications during hospitalisation, number of hospital (re)admissions and

outpatient visits during the study period, number of unexpected intensive care

admissions, 30 days and 1 year mortality.

Study description

Background summary

Colorectal cancer (CRC) disproportionately affects patients aged 70 years and older. Surgery is the main treatment modality for CRC, but is associated with increased risk of postoperative morbidity, disability and loss of health related quality of life (HRQL). Frailty is an age related state of functional decline and considered to be an important risk factor for adverse outcome in geriatric oncology. Risk models for adverse outcome may be used for treatment decisions in the elderly, but are often not designed to predict patient related outcome measures and do not include frailty characteristics.

Study objective

1. To determine the predictive value of frailty characteristics for loss of HRQL in elderly patients with non-metastatic CRC.

2. To develop an AGE-CRC score, a prediction model for loss of HRQL in elderly patients with CRC based on comorbidity, risk factors and frailty.

Study design

Multicentre, prospective, observational cohort study with a follow up time of one year. After initial diagnosis of CRC subjects will be screened for frailty using validated questionnaires, physical tests and non-invasive measurements. Frailty characteristics and HRQL are determined by Geriatric 8 (G8), Hospital Anxiety and Depression Scale(HADS), Euroqol- 5 dimensional (EQ-5D), Lawton Instrumental Activities of Daily Living scale(IADL), Mini Nutrition Assessment (MNA), 6 Item Cognitive Impairment Test (6-CIT), Identification of Seniors At Risk * Hospitalized Patients(ISAR-HP) and the EORTC-QLQ-C30/CR29 (HRQL in CRC patients). Physical tests include the Timed to Get Up (TUG) test and the hand grip strength test. Furthermore, the non-invasive measurements consist of a sarcopenia analysis using an existing CT/MRI scan and measurement of Advanced Glycation Endproducts (AGE reader).
Additional patients characteristics including medication use, medical history and laboratory results of preoperative routine blood sampling will be collected. At three, six and twelve months after surgery or diagnosis, EORTC QLQ-C30/EORTC QLQ-CR29 and EQ-5D questionnaires are used to determine HRQL and disability free survival.

Study burden and risks

Frailty screening will be performed in all study patients with a new diagnosis of non-metastatic CRC and will approximately take 40 minutes per patient. This is an observational study, there are no expected risks associated with frailty screening. Participation in this study will not conflict with standard care and will not delay diagnosis or treatment. There is no individual benefit for the participating subjects. Currently little is known about the relation between frailty and HRQL after CRC surgery/diagnosis. No risks are expected as the subjects will be treated similar to patients who dot no participate. If this study shows that a risk model including frailty characteristics is predictive for loss of HRQL after CRC surgery, implementation of this model (after validation) in standard care should be considered.

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 * 70 years
Histologically proven non-metastatic colorectal cancer

Exclusion criteria

Emergency surgery
Insufficient understanding of the Dutch language

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-08-2017
Enrollment:	340
Type:	Actual

Ethics review

Approved WMO Date:	07-07-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-08-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-10-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL61523.100.17