Identifying patients with hereditary and familial colorectal cancer by using an online risk tool

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28822

Source
NTR

Brief title
FR-QUENT study

Health condition

colorectal cancer, questionnaire, heredity, Lynch syndrome, familial colorectal cancer, family history

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: Dutch Digestive Foundation (Maag Lever Darm Stichting)

Intervention

Outcome measures

Primary outcome

Percentage of all included patients who receive a recommendation for regular surveillance

colonoscopies for himself/herself and/or relatives, provided by a clinical geneticist.

Secondary outcome

-Percentage of all included patients with a referral to a clinical geneticist

-Percentage of referred patients fulfilling referral criteria for a Lynch syndrome suspicion

-Percentage of all included patients with genetically confirmed Lynch syndrome

-Percentage of all included patients with confirmed other hereditary CRC syndromes (such as polyposis syndromes)

-Percentage of referred patients fulfilling FCC criteria

-Percentage of all included patients who receive a surveillance advice per time period (month or season)

-Percentage of referred patients not fulfilling referral criteria for FCC, a Lynch syndrome suspicion or other hereditary CRC syndromes

-All the above mentioned outcome measures per hospital

-Percentage of patients not adhering to referral advice

-The number of changes in family history after verification of the completed questionnaire at the outpatient clinic

-Reasons for not filling out the questionnaire at home or at all

-Usability of the questionnaire for health care providers and patients

Study description

Background summary

In this trial we will evaluate the effectiveness of the implementation of a digital familial risk questionnaire in the detection of CRC patients with hereditary or familial CRC. This will be done using a stepped wedge design with 5 participating hospitals for a duration of 1.5 years. A comparion is made between an intervention phase (offering the online risk assessment questionnaire) and a control phase (hospital-based standard practice for the detection of CRC patients with hereditary or familial CRC, informed by the referral criteria that are being used in the intervention group). All patients with a diagnosis of CRC who have a first appointment at the CRC outpatient clinic will be included. The primary outcome is the percentage of all

included patients who receive a recommendation for regular surveillance colonoscopies for himself/herself and/or relatives, provided by a clinical geneticist. Data from clinical geneticists is being used to answer this question.

Study objective

Our aim is to increase the detection of patients with CRC with familial or hereditary CRC in order to give them an optimal CRC treatment as well as a suitable surveillance advice, and to enable the patient to inform family members about this risk so they can subsequently be referred for evaluation.

The primary objective of this study is to evaluate the effectiveness of the implementation of a digital familial risk questionnaire in the detection of CRC patients with familial or hereditary CRC.

Study design

Primary and secondary outcomes will be assessed every 2 months by searching for reports on clinical genetics consultation in medical files of included patients and if found, they can be used to answer to primary and secondary outcomes. In order not to miss any referral information, a check with local genetic centers will be done.

Secondary outcome measures, to be calculated in the intervention group only:

-Percentage of patients not adhering to referral advice. This outcome applies to patients who should be referred to a clinical geneticist based on the automatic referral advice. Adherence will be checked by verifying records on clinical genetics consultations. Involved nurses or gastroenterologists will contact these patients if no records on clinical genetics consultations are found six months after the visit to the CRC outpatient clinic.

-The number of changes in family history after verification of the completed questionnaire at the outpatient clinic. For each patient, a box can be ticked by a nurse or gastroenterologist indicating the number of answers that were changed (none, >5 or <5 changes).

-Reasons for not filling out the questionnaire at home or at all. For each patient that does not want to complete the questionnaire, the best fitting reason can be ticked from a list by a nurse or gastroenterologist after verifying with the patient.

-Usability of the questionnaire for health care providers and patients. At the end of the study all participating nurses and gastroenterologists will be given a short questionnaire with several questions about their opinion of the online questionnaire. A small number of patients will also be given a questionnaire with several questions about their opinion of the online

questionnaire.

Intervention

Intervention: offering an online risk assessment questionnaire to CRC patients, to facilitate the detection of CRC patients with hereditary or familial CRC

Control: Hospital-based standard practice for the detection of CRC patients with hereditary or familial CRC, informed by the referral criteria that are being used in the intervention group

Contacts

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Eligibility criteria

Inclusion criteria

Patients with a diagnosis of CRC who have a first appointment at the outpatient clinic (before treatment has started). If a patient undergoes surgery before going to an outpatient clinic (in case of an acute surgery indication), this patient will not be included in our study

Exclusion criteria

Patients who have received a CRC treatment before their intake visit will be excluded

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2015
Enrollment:	104
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-08-2015
Application type:	First submission

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
NTR-new	NL5291
NTR-old	NTR5398
Other	Medical Ethics Committee Academic Medical Center : 14_301#14.17.0363

Study results