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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28822

Bron
NTR

Verkorte titel
FR-QUENT study

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center
Overige ondersteuning: Dutch Digestive Foundation (Maag Lever Darm Stichting)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Percentage of all included patients who receive a recommendation for regular surveillance colonoscopies for himself/herself and/or relatives, provided by a clinical geneticist.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2015
Aantal proefpersonen:	104
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-08-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5291
NTR-old	NTR5398
Ander register	Medical Ethics Committee Academic Medical Center : 14_301#14.17.0363

Resultaten