Catch the cancer; towards a cfDNA-based test for colorectal cancer screening

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cfDNA can be used to develop a reliable bloodtest for identification of advanced adenoma and colorectal cancer

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

Summary

ID

NL-OMON29451

Source
NTR

Brief title
CATCA

Health condition

Lynch syndrome, colorectal cancer

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Erasmus MC, department of Clinical Genetics

Intervention

Outcome measures

Primary outcome

The agreement between cfDNA profiles and DNA profiles of corresponding lesions (advanced

adenomas, CRC)

Secondary outcome

The psychological impact of this cfDNA-based blood test.

Study description

Background summary

Introduction of the national screening program for colorectal cancer (CRC) has improved the prevention and early detection of this disease. The screening consists of a fecal immunohistochemical test for hemoglobin (FIT), which is followed by a colonoscopy if positive. Nevertheless, the FIT's sensitivity and specificity are still low, leading to an unnecessary colonoscopy in half of the FIT positive individuals. Patients with Lynch Syndrome (LS) are advised to undergo surveillance colonoscopies every two years. However, a colonoscopy is burdensome, and it doesn't provide detection of extra colonic cancers associated with LS. A reliable, more efficient test is needed to identify individuals with adenomas and/or early carcinomas, both sporadic as LS-associated. For this purpose, a blood test based on cell free DNA (cfDNA) might have potential. This test is currently used to monitor tumor activity in cancer patients. Therefore, we hypothesize that cfDNA analysis can also be used as a non-invasive screening test for precursor lesions and/or early cancer. Thus, our primary objective is to develop a cfDNA based screening/surveillance tool for colorectal adenoma and cancer, both in the setting of the national CRC screening program and in the surveillance of LS carriers. Secondarily, we aim to evaluate the psychological impact of this new way of cancer screening for patients (especially regarding incidental findings).

Study objective

cfDNA can be used to develop a reliable bloodtest for identification of advanced adenoma and colorectal cancer

Study design

Inclusion of participants: starting June 2020

Intervention

Drawing blood, questionnaires

Contacts

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Eligibility criteria

Inclusion criteria

Lynch syndrome carriers (of at least 18 years of age) being under surveillance in our centre that granted informed consent to participate in our study OR participants from the national CRC screening program with a positive FIT that granted informed consent to participate in our study.

Exclusion criteria

Individuals participating in the Dutch national CRC screening program who are known to be carrier of a genetic predisposition for CRC (for example Familial Adenomatous Polyposis or MUTYH Associated Polyposis), or have a negative FIT, or have a positive FIT with sequential colonoscopy already performed, or are unwilling to undergo colonoscopy or to receive unexpected, but relevant and actionable findings, or underwent a failed colonoscopy; and LS carriers who are unwilling to undergo colonoscopy or to receive unexpected, but relevant and actionable findings, who are <18 years, who underwent a failed colonoscopy.

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2020
Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	10-06-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48193
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8695

Register	ID
CCMO	NL68955.078.19
OMON	NL-OMON48193

Study results