Non-invasive markers for colorectal cancer screening.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23263

Source
NTR

Brief title
N/A

Health condition

colorectal cancer, colorectal neoplasia, colorectal neoplasms, high risk population, family history

Sponsors and support

Primary sponsor: Maastricht University Medical Center
Source(s) of monetary or material Support: Maastricht University Medical Center

Intervention

Outcome measures

Primary outcome

Diagnostic accuracy of molecular and protein markers in screening for colorectal neoplasia in subjects at high-risk for CRC and CRC patients, in comparison with average-risk subjects.

Secondary outcome

The role of non-invasive markers in risk stratification of patients at high-risk for CRC.

Study description

Background summary

Rationale: Colonoscopy is considered to be the gold standard for the detection of colorectal neoplasia. However, this method has important disadvantages, such as invasiveness, complication risk, and possible shortage of clinical capacity. Therefore, the potential additional role of non-invasive screening methods as pre-selection tool for colonoscopy, deserves further investigation. Non-invasive markers for CRC have recently been developed for blood and feces. These markers are currently tested in an average-risk population. In patients at high-risk, as a result of a positive family history, the clinical utility of these markers as pre-selection tool has not been investigated yet. Likewise, no data are available regarding the potential role of these markers in risk stratification of these patients. The clinical utility of such markers to identify risk profiles and hence, to design more individualized surveillance strategies, deserves further investigation.

Objective:

Two issues will be addressed:

I. To study the diagnostic accuracy of molecular and protein markers in screening for colorectal neoplasia in subjects at high-risk for CRC and CRC patients, in comparison with average-risk subjects.

II. To investigate the role of non-invasive markers in risk stratification of patients at high-risk for CRC. To provide insights in the molecular features of patients at high-risk.

Study design:

For this purpose, a prospective, cross-sectional study will be performed. The following groups of patients will be included:

i) 200 patients with a family history of CRC and

ii) 150 patients diagnosed with CRC.
Medical data will be collected, all subjects will undergo colonoscopy and non-invasive markers for colorectal neoplasia will be investigated in blood and fecal samples. Additionally, a subset of patients with a non-colorectal gastrointestinal malignancy (e.g. esophageal,

gastric or pancreatic cancer) will be included in order to investigate the influence of these lesions on the non-invasive markers profile.

Study objective

Non-invasive markers have an additional role in screening and surveillance of patients at high risk for CRC.

Study design

2 years

Intervention

Collection of blood and fecal samples (once). Non-invasive markers for colorectal neoplasia will be determined in blood, feces and tissue. All combinations of markers will be tested in order to optimize the diagnostic accuracy for colorectal neoplasia, considering the outcome of colonoscopy as the gold standard. In addition the results of the non-invasive markers in patients at high-risk will be compared with the results of an average-risk population, in order to identify risk factors.

Contacts

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Eligibility criteria

Inclusion criteria

- This population will include patients with hereditary forms of CRC (Lynch syndrome or FAP) as well as patients fulfilling the criteria for familial CRC syndrome:

i) ³ 1 first degree relative (FDR) with CRC diagnosed < 50 year or

ii) ³ 2 FDR with CRC diagnosed between 50-70 year or

iii) 1 FDR and 1 second degree relative with CRC diagnosed < 70 year.

- Furthermore patients diagnosed with CRC will be included.

Exclusion criteria

Individuals will be excluded if:

1. Younger than 18 years of age

2. Diagnosed with inflammatory bowel disease (Crohn’s disease or ulcerative colitis)

3. Diagnosed with major co-morbidity which may interfere with the outcome of the study (e.g. severe cardiovascular or pulmonary disease, other malignancies)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2008
Enrollment:	410
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL1318
NTR-old	NTR1367
Other	: MEC 08-2-038
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A