Non-invasive markers for colorectal neoplasia
A multi-marker approach in screening for colorectal cancer

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Objective: Two issues will be addressed:I. To study the diagnostic accuracy of molecular and protein markers in screening for colorectal neoplasia in subjects with either a low-risk or a high-risk for CRC.II. To define a multi-marker approach for…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON31896

Source
ToetsingOnline

Brief title
Non-invasive markers for colorectal neoplasia

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
cancer of the large bowel, colorectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: colorectal neoplasia, non-invasive, risk-groups, screening

Outcome measures

Primary outcome

Test characteristics (sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy) of different molecular and protein markers in the detection of colorectal neoplasia in patients with a low-risk or high-risk for CRC.

Secondary outcome

The identification of risk factors for colorectal neoplasia in subjects at low-risk and at high-risk for CRC. Subsequently, a multi-marker approach for risk stratification in these groups of individuals at different risks for CRC will be designed.

Study description

Background summary

Rationale:
Colorectal cancer (CRC) is a major health issue in the Netherlands. Screening is mandatory to decrease the incidence of CRC and the disease related mortality. However, the lack of consensus on a single best screening method reflects the limitations of all currently available strategies. Two groups at risk for CRC are identified: individuals older than 50 years (low-risk subjects) and patients with a family history of CRC (high-risk subjects). Screening in these two groups seems justified. At this moment, the best screening method for the low-risk group is being investigated in different medical centres in the Netherlands. For patients at high-risk, surveillance by colonoscopy is indicated following the national guidelines. Colonoscopy is considered to be the golden standard for detection of colorectal neoplasia.

However, this method has important disadvantages such as invasiveness, complication risk, and possible shortage of clinical capacity. Therefore other, non-invasive, screening methods deserve further investigation.
Non-invasive markers for CRC have been recently developed for blood and faeces. These markers are currently tested in individuals at low-risk in a workplace based screening population. In patients at high-risk, as a result of positive family history, the clinical utility of these markers has not been investigated yet.

Study objective

Objective:
Two issues will be addressed:
I. To study the diagnostic accuracy of molecular and protein markers in screening for colorectal neoplasia in subjects with either a low-risk or a high-risk for CRC.
II. To define a multi-marker approach for risk stratification in these populations at different risks for CRC.

Study design

Study design:
For this purpose, a prospective, cross-sectional study will be performed. The following groups of patients will be included: i) 400 individuals participating in the workplace based CRC screening study, ii) 200 patients with a family history of CRC and iii) 150 patients with proven CRC. Medical data will be collected, all subjects will undergo colonoscopy and non-invasive markers for colorectal neoplasia will be investigated in blood and faeces samples. Additionally, a subset of patients with a non-colorectal gastrointestinal malignancy (e.g. oesophageal, gastric or pancreatic cancer) will be included in order to investigate the influence of these lesions on the test results of the non-invasive markers.

Study burden and risks

Burden and risks:
venapuncture: local pain and hematoma are possible adverse events
collection of faeces sample: no risks, may be uncomfortable for participant

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

Subjects who will undergo a colonoscopy.
1) average-risk population
Employees (50-65 years of age) from companies participating in the ongoing workplace-based CRC screening project by colonoscopy have already been included.
2) high-risk population
Patients with a positive family history of CRC visiting the *outpatient clinic for hereditary colorectal cancer* or visiting the endoscopy unit of the MUMC+ for surveillance colonoscopy will be asked to participate into the study. 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.
3) CRC patients
Patients diagnosed with CRC, visiting the *emergency outpatient clinic* of the Division of Gastroenterology-Hepatology after the initial diagnosis of CRC and before subsequent therapeutic interventions are started, will be included.
Additionally, a subset of patients diagnosed with either oesophageal, gastric or pancreatic cancer will be included at our *emergency outpatient clinic* of the Division of

Gastroenterology-Hepatology after initial diagnosis and before subsequent therapeutic interventions are started. We will include 20 patients for each group of non-colorectal gastrointestinal malignancy.

Exclusion criteria

Individuals will be excluded if:
-younger than 18 years old
-diagnosed with inflammatory bowel disease (Crohn*s disease or ulcerative colitis)
-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 invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-05-2009
Enrollment:	410
Type:	Actual

Ethics review

Approved WMO

Date:	29-08-2008
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL22905.068.08