Biobank for development of screening markers for colorectal neoplasia. Translational research in colorectal cancer and adenomas.

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Implementation of a biobank infrastructure to facilitate development and improvement of screening markers for colorectal neoplasia. New biomarkers will be compared to state of the art tests, e.g. currently FIT.

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

Summary

ID

NL-OMON37786

Source ToetsingOnline

Brief title

Biobank for development of screening markers for colorectal neoplasia

Condition

• Malignant and unspecified neoplasms gastrointestinal NEC

Synonym

Coloncancer. Large polyps.

Research involving Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

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Source(s) of monetary or material Support: CTMM project DeCoDe (Decrease Colorectal Cancer Death)

Intervention

Keyword: Biobank, Colorectal neoplasma, Screeningmarker

Outcome measures

Primary outcome

Collection of faeces for development and improvement of new biomarkers for CRC.

Development of a stool test with a (panel of) molecular marker(s).

Endpoints for evaluation of screening markers: presence of CRC and advanced

adenomas (advanced neoplasia).

The following test characteristics are used as primary outcome measurements for

the different biomarkers.

- Sensitivity
- Specificity
- Positive predictive value (PPV)
- Negative predictive value (NPV)

Secondary outcome

Quality and stability of samples collected.

Study description

Background summary

Colorectal cancer (CRC) is one of the three malignancies with highest incidence and mortality in the industrialized world. Population based screening is likely to be the most effective strategy to decrease CRC related mortality. Screening by guaiac-based faecal occult blood tests (g-FOBT) has shown to decrease CRC related mortality. Even though faecal immunochemical tests (FITs) have shown superior performance over g-FOBTs, test performance is still suboptimal. Previous studies on detection of exfoliated tumour specific (methylated) DNA and proteins in faeces showed promising results. However, translation of such findings from basic research towards daily practice is hampered by a limited sample size and lack of prospective study design.

Study objective

Implementation of a biobank infrastructure to facilitate development and improvement of screening markers for colorectal neoplasia. New biomarkers will be compared to state of the art tests, e.g. currently FIT.

Study design

Prospective cohort study.

Study burden and risks

Burden for participant contains at home faeces collection.

Contacts

Public Vrije Universiteit Medisch Centrum

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

All subjects 40 years of age or older scheduled for colonoscopy will be invited to participate. Subjects with colorectalcancer (CRC) or advanced adenomas detected at colonoscopy will be included as cases, whereas subjects without advanced neoplasia will be included as controls. All subjects should be capable to give informed consent. All subjects should speak and understand the Dutch language

Exclusion criteria

- Subjects < 40 years of age
- No informed consent
- Subjects with IBD/sigmoidoscopy or colonoscopy in the past four weeks/extended hemicolectomie/colostomy
- Subjects who received chemotherapy in the past three weeks
- Hospitalized individuals

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

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Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	19-07-2012
Enrollment:	3500
Туре:	Actual

Ethics review

Approved WMO	
Date:	06-07-2012
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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 CCMO ID NL38872.094.11