Molecular stool testing for colorectal cancer surveillance

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26772

Source
NTR

Brief title
MOCCAS

Health condition

colorectal cancer, surveillance, molecular stool testing

colorectaal carcinoom, surveillance, moleculaire ontlastingstest

Sponsors and support

Primary sponsor: prof. dr. P. Fockens
Meibergdreef 9, room C2-330
1105 AZ Amsterdam, the Netherlands
email: p.fockens@amc.uva.nl
tel: +31 20 5663408
Source(s) of monetary or material Support: Dutch Cancer Society/KWF - Alpe d'Huzes

Intervention

Outcome measures

Primary outcome

1. The accuracy (sensitivity, specificity, PPV and NPV) of the molecular stool test (Cologuard®) and FIT compared to colonoscopy in the detection of advanced neoplasia in a surveillance population.

2. Health outcomes and cost-effectiveness of multiple surveillance strategies based on accuracies from endpoint 1.

Secondary outcome

- The presence of the molecular markers (included in the molecular stool test) in the resected polyps;

- The correlation between the presence of the molecular markers and the result of the molecular stool test;

- The identification of low- and high risk adenomas based on previously identified progression biomarkers in all the post-polypectomy tissue samples;

- The impact of molecularly defined high-risk adenoma's on the obtained sensitivity data of the molecular stool test (Cologuard®) and FIT;

- The impact of the integration of molecularly defined high-risk adenoma's on the health outcomes and cost-effectiveness of the multiple surveillance strategies.

- The additional value of risk assessment through a questionnaire (addressing gender, age, BMI20,21, family history22,23, physical activity, nutritional habits and smoking) on the accuracy of the molecular stool test (Cologuard®) and FIT.

Study description

Background summary

Since January 2014 the Dutch screening programme for bowel cancer has been implemented. Screening will increase the demand for surveillance. Although patients in whom adenomas have been removed are at increased risk of progressing to cancer, solid evidence on the reduction of death from CRC through the current colonoscopy-based surveillance is lacking. Furthermore, colonoscopy-based surveillance leads to high logistic demands, high individual burden and high costs. Therefore, there is need for new surveillance strategies. Stool-based molecular testing (Cologuard®, consisting of a stool DNA test and an immunochemical assay for human hemoglobin) or Faecal Immunochemical Testing (FIT) may serve as an alternative for colonoscopy surveillance.

Objectives: 1. To compare the accuracy of an established molecular stool test (Cologuard®) and FIT to colonoscopy for detection of advanced adenomas or CRC (advanced neoplasia) in

a surveillance population.

2. To model various strategies of stool-based molecular surveillance to inform health policy decisions.
Study design: Prospective observational cross-sectional cohort study.

Study population: Persons with a scheduled surveillance colonoscopy (age 50-75 year) in one of the participating centers.

Intervention: Collection of whole-stool samples for stool testing primary to surveillance colonoscopy and the completion of a questionnaire.

Main study parameters/endpoints:

1. The accuracy (i.e. sensitivity, specificity, positive- and negative predictive value) of the molecular stool test (Cologuard®) and FIT in the detection of advanced neoplasia compared to colonoscopy.

2. Model-based predictions of long-term health outcomes and cost-effectiveness of multiple surveillance strategies based on accuracies from endpoint 1.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Burden for participant consists of at home faeces collection, performance of FIT and the completion of a questionnaire.

Study objective

Surveillance using a molecular stool test could serve as an alternative for the current method that is based on colonoscopy

Study design

In order to compare the results of the molecular stool test and FIT and subsequently model various surveillance strategies, no follow up is needed. Therefore: timepoint = 0

Intervention

Collection of whole-stool samples for stool testing primary to surveillance colonoscopy and the completion of a questionnaire.

Contacts

Public
Meibergdreef 9, room B1-245

MCJ van Lanschot
Amsterdam 1105 AZ
The Netherlands
+31 20 5662806
Scientific
Meibergdreef 9, room B1-245

MCJ van Lanschot
Amsterdam 1105 AZ
The Netherlands
+31 20 5662806

Eligibility criteria

Inclusion criteria

Amendment 3-jun-2016:
- Subjects in the age group 50-75 years. The lower age limit is set at 50 years because of the high probability of familiar predisposition when advanced neoplasm is present in a younger age group.26 The upper age limit of 75 years is in correspondence with the recommended stop-age for surveillance according to the current guideline.

- Subjects with an indication for surveillance colonoscopy according to the previous guideline ('Follow up after polypectomy', 2002; summarized in 2008) or current ('Colonoscopy Surveillance', 2013) guideline, including subjects with a history of CRC or polypectomy, as well as subjects under surveillance for familial colorectal carcinoma (FCC)

- Subjects who have sufficient comprehension of the Dutch language.

- Subjects who have given their informed consent.

Exclusion criteria

Amendment 3-jun-2016:
- Subjects with inflammatory bowel disease (IBD)

- Subjects with Lynch syndrome, familial adenomatous polyposis (FAP), attenuated FAP (AFAP), MUTYH associated polyposis (MAP) and serrated polyposis syndrome (SPS)

- Previous colonoscopy < 6 months (rescopy)

- Subjects with proctocolectomy

- Subjects with life expectancy < 3 years

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2015
Enrollment:	4000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	28-07-2015
Application type:	First submission

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	NL5183
NTR-old	NTR5331
Other	METC : 2015_070

Study results