Molecular stool testing for colorectal cancer surveillance

Gepubliceerd: 28-07-2015 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26772

Bron
Nationaal Trial Register

Verkorte titel
MOCCAS

Aandoening

colorectal cancer, surveillance, molecular stool testing

colorectaal carcinoom, surveillance, moleculaire ontlastingstest

Ondersteuning

Primaire 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
Overige ondersteuning: Dutch Cancer Society/KWF - Alpe d'Huzes

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Meibergdreef 9, room B1-245

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

Wetenschappelijk

Meibergdreef 9, room B1-245

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2015
Aantal proefpersonen:	4000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	28-07-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5183
NTR-old	NTR5331
Ander register	METC : 2015_070

Resultaten