Fecal Immunochemical Testing as a Tool to Determine the Need for Colonoscopy in Symptomatic Patients

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Using two FIT tests in symptomatic patients prior to colonoscopy can be a useful preselection tool to determine the need for colonoscopy in symptomatic patients.

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

Samenvatting

ID

NL-OMON20343

Bron
NTR

Verkorte titel
FITNESS

Aandoening

Colorectal cancer

Ondersteuning

Primaire sponsor: Erasmus MC (s-Gravendijkwal 230 3015 CE Rotterdam P.O. Box 2040, 3000 CA Rotterdam Phone: +31 10 704 0704) and Sysmex Europe (Postbus 251 4870 AG Etten-Leur Phone: +31(0)765086000)
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The performance of 2-sample FIT to detect advanced neoplasia by defining its negative predictive value, positive predictive value, sensitivity and specificity.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: In patients with bowel symptoms a colonoscopy is performed to rule out or diagnose a clinical relevant lesion. In most of these colonoscopies a significant abnormality is not found. However, colonoscopy is not without risk, is time-consuming, may cause discomfort and is costly. In order to decrease the number of unnecessary colonoscopies, high risk symptom based referral criteria for colonoscopy have been developed (e.g. NICE criteria). However, symptoms alone are poor predictors of the underlying pathology. Noninvasive
faecal immunochemical testing (FIT) could be a useful preselection tool to
determine the need for colonoscopy in symptomatic patients. Earlier studies have shown that FIT has very high negative predictive values for colorectal cancer (CRC) ranging from 99-100%, suggesting it could be used to rule out CRC and avoid colonoscopy. Up until now, studies showing this considerable potential of FIT included small groups of patients. Larger studies are needed to give a more reliable conclusion. Also, studies focus mainly on ruling out CRC, while also high negative predictive values for advanced adenomas (AA) are warranted to prevent patients to develop CRC in the (near) future. Studies have shown lower negative predictive values of around 95% for advanced neoplasia (CRC and AA) then for CRC alone. Some studies have hypothesized that doing two FIT’s might result in higher negative predictive values, but research on this topic is scarce.

Objective: To evaluate the performance of two-sample FIT as a preselection tool for colonoscopy in symptomatic patients.

Study design: Prospective observational cohort study.

Study population: 807 symptomatic patients referred for diagnostic colonoscopy.
Intervention: Subjects will be asked to complete two FIT’s prior to their colonoscopy.

Main study parameters/endpoints: Performance of two FIT’s in two executive bowel movements to assess the yield of advanced neoplasia in symptomatic patients (negative predictive value, positive predictive value, sensitivity and specificity).

Doel van het onderzoek

Using two FIT tests in symptomatic patients prior to colonoscopy can be a useful preselection tool to
determine the need for colonoscopy in symptomatic patients.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

Erasmus MC
Manon Spaander

N/A

Wetenschappelijk

Erasmus MC
Manon Spaander

N/A

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Referral for a diagnostic colonoscopy because of (new) bowel symptoms.
2. Able to undergo colonoscopy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Subjects will be excluded if they are referred for colonoscopy surveillance for other indications (including hereditary CRC syndrome, familial CRC syndrome, inflammatory bowel disease, history of colorectal adenoma or CRC)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2019
Aantal proefpersonen:	807
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:	15-08-2019
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	NL7966
Ander register	METC Erasmus MC : MEC-2019-0381

Resultaten