Comparison study of two fecal immunochemical tests within a nationwide colorectal cancer screening program

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Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26021

Bron
Nationaal Trial Register

Verkorte titel
Vergelijkende studie

Aandoening

screening, colorectal cancer

Ondersteuning

Primaire sponsor: Erasmus Medical Centre
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

detection rate of advanced neoplasia

Toelichting onderzoek

Achtergrond van het onderzoek

Colorectal cancer(CRC) is the second cause of cancer related death in the Netherlands, accounting for over 5100 deaths per year. Due to its high frequency, mortality and morbidity rate and the high socio-economic burden associated with this disease, CRC has become an important and challenging public health problem. The European Code against Cancer recommends that men and women from 50 years of age participate in CRC screening programs. Nationwide screening programs are currently being implemented in several European countries including the Netherlands. Faecal immunochemical tests (FIT, i.e. immunochemical FOBT) are recommended for population-based screening programs. In the Netherlands, a national population-screening program for CRC is implemented from February 2014 onwards and will be rolled out in 5 years. The program is based on biennial testing with a single, quantitative FIT. The results of pilot-programs in the regions of Amsterdam, Nijmegen and Rijnmond have largely contributed to this nationwide program. Different types of FIT are available on the market. So far, all Dutch pilot studies were performed with the OC-Sensor test (Eiken, Japan), whereas for the nationwide program another type of FIT has been selected by a tender: the FOB-Gold (Sentinel, Italy). Only sparse data on screening with the FOB-Gold are available and none of the previous studies simulated the Dutch population screening setting. In a recently published head-to-head comparison between FOB-Gold and OC-Sensor, 37,999 invitees were invited in a Spanish pilot screening program. This study showed higher true positive rates among OC sensor users, and higher (false) positive rates in FOB Gold users. Another finding in this study was a difference in absolute participation rate of 2-3% in favour of the OC-sensor. The reason for this observed difference is unknown, as the investigators did not survey participants or analyse ease of use of the tests. Data on participation rates, as well as test performance, positivity rate, diagnostic yield and practical use should be obtained in the current Dutch population-based screening setting. Such evidence could be used to further optimize implementation of our nation-wide screening program and would justify adjustments to be made in the program. To obtain unbiased estimates of the practical use of both tests, data should be collected in a population that has not yet been screened by FIT.

We therefore plan to perform an unpaired and paired design trial comparing both FITs. This study will be performed within the target-population for the nationwide screening program in the South-West region of the Netherlands. For the primary outcome measures positivity rate, diagnostic yield and practical use, we aim to estimate that FOB-Gold is similar to OC-Sensor in a paired design. A potential difference in participation rate between both FIT tests will be estimated in the unpaired design. In total 44,038 invitees will be randomly allocated to receive the OC-Sensor (2019 invitees, the FOB-Gold FIT (2019 invitees) or both FITs (40,000 invitees). All study participants with a positive FIT will be invited to a certified colonoscopy centre, as is required in the nation-wide screening program, to undergo a colonoscopy by a certified endoscopist. An additional scope of this call is to establish procedures, logistics and infrastructure for research performed within the national screening program. We aim to perform the study within the logistics of the current nationwide screening program. Primary

outcome measures of our study proposal are participation, positivity rate, diagnostic yield and practical use. In additional analyses we will study the effect of gender, age, smoking and drinking habits, medication use, ethnicity and socio-economic status on the primary outcome measures and calculate conditional differences between the two tests.

Onderzoeksopzet

n.a.

Onderzoeksproduct en/of interventie

Screenees will receive two FITs (OC-sensor, Eiken Japan and FOB-Gold, Sentinel) to sample from one bowel movement.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

Average risk persons aged 55-75 years old in the South-West region. We will invite all persons from the national screening program in this region, who are recruited by random selection from the nationwide screening database.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria for colonoscopy are: underwent proctocolectomy; is currently treated for colorectal cancer; is currently treated for IBD; terminal disease (life-expectancy < 5 years); inability or refusal to provide informed consent.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-05-2016
Aantal proefpersonen:	44038
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL5721
NTR-old	NTR5874
Ander register	: 769500-135716-pg

Resultaten