

Various aspects of FIT-screening: a 4th screening round.

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There is no difference in test performance between the OC-sensor and FOB-Gold in a 4th round of FIT-screening.

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

Samenvatting

ID

NL-OMON23322

Bron

NTR

Aandoening

FIT, screening, colorectal cancer, advanced neoplasia, bevolkingsonderzoek darmkanker, FOBT

Ondersteuning

Primaire sponsor: Academic Medical Centre

Erasmus Medical Center

Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Participation, positivity rate, diagnostic yield and practical use for two types of FITs (OC-Sensor and FOB-Gold)

Toelichting onderzoek

Achtergrond van het onderzoek

Colorectal cancer (CRC) is one of the major causes of death in the Netherlands, accounting for over 5100 deaths in 2010.

Population screening aims to detect CRC in an earlier phase, thereby reducing CRC morbidity and mortality. In the Netherlands, population screening for CRC is currently being implemented based on biennial testing with a single, quantitative fecal immunochemical test (FIT, i.e. immunochemical FOBT). Whereas several FITs are available on the market, all pilot-studies in our country were performed with the OC-Sensor test (Eiken, Japan). The tender for the nationwide program however, has been allocated to another FIT: the FOB-Gold (Sentinel, Italy). Only sparse data on screening with the FOB-Gold are available without a head-to-head comparison between FOB-Gold and OC-Sensor regarding participation rates, test characteristics and practical use. We plan a randomized controlled trial for a 4th round of biennial FIT-screening in the combined dynamic cohorts of Amsterdam and Rijnmond, consisting of approximately 22.000 persons aged 50-75. Invitees will be randomized to receive either the OC-Sensor or the FOB-Gold FIT. The cut-off level for positivity of both tests will be the lowest level that is technically achievable, enabling comparison and modeling for different cut-off levels. All persons with a positive test-result will be referred for colonoscopy. Primary outcome will be differences between the two types of FIT for participation, positivity rate, diagnostic yield and practical use.

Doel van het onderzoek

There is no difference in test performance between the OC-sensor and FOB-Gold in a 4th round of FIT-screening.

Onderzoeksopzet

n.a.

Onderzoeksproduct en/of interventie

n.a.

Contactpersonen

Publiek

E.J. Grobbee
Rotterdam

The Netherlands

Wetenschappelijk

E.J. Grobbee
Rotterdam
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Average risk persons aged 50-75 years old in the Amsterdam and Rijnmond region. We will invite all persons from the dynamic cohort of approximately 22.000 persons that were invited in the previous rounds and were originally recruited by random selection in the city population database (Gemeentelijke Basis Administratie, GBA).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria for colonoscopy are: complete colonoscopy or CT-colonography performed within the last 2 years; severe co-morbidity (ASA IV/V); terminal disease (life-expectancy < 5 years); inability or refusal to provide informed consent.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2014
Aantal proefpersonen:	20000
Type:	Werkelijke 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	NL5278
NTR-old	NTR5385
Ander register	WBO: 161536-112008-PG : ZonMw: 50-51515-98-302

Resultaten

Samenvatting resultaten

n.a.