

Two-sample FIT-screening: a 4th screening round

Gepubliceerd: 11-03-2016 Laatst bijgewerkt: 13-12-2022

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

Samenvatting

ID

NL-OMON20828

Bron

NTR

Verkorte titel

CORERO

Aandoening

colorectal cancer, screening, darmkanker

Ondersteuning

Primaire sponsor: Erasmus Medical Center

Overige ondersteuning: funder = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Participation, positivity rate, diagnostic yield of two-sample FIT screening.

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. Long-term randomized prospective trials using guaiac-based fecal occult blood testing (gFOBT) have proven to decrease CRC related mortality. Currently the classical gFOBT is being replaced by the fecal immunochemical test (FIT), as FIT is more specific to lower-digestive tract blood loss and leads to higher participation and detection rate. While gFOBT samples on multiple consecutive bowel movements, standard FIT only uses one sample from one bowel movement. Since advanced neoplasia can bleed intermittently, it may be missed with single stool sampling. Screening by means of a 2-sample FIT can reduce the risk of missing advanced lesions, and therefore increase test sensitivity. People aged 50-75 years will receive two identical FITs (OC-sensor, Eiken Japan) to sample from two consecutive bowel movements.

The cut-off level for positivity will be 10 µg hemoglobin per gram feces, which is the lowest level used worldwide, enabling comparison and modeling for different cut-off levels. Participants with at least one positive test will be offered colonoscopy.

We aim to determine participation and diagnostic yield of repeated 2-sample FIT screening. We will also compare these data with repeated 1-sample FIT screening to assess the additional yield of 2-sample FIT screening to current screening strategies. We will focus on cumulative yield after four rounds, as well as comparing yield per round. These data will give us insight in alternative screening strategies and provides the opportunity to optimize implementation of the nation-wide colorectal cancer screening program.

Onderzoeksopzet

n.a.

Onderzoeksproduct en/of interventie

People will receive two identical FITs (OC-sensor, Eiken Japan) to sample from two consecutive bowel movements.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Average risk persons aged 50-75 years old in the Rotterdam-Rijnmond region. We will invite all persons from the dynamic cohort of approximately 3200 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:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2015
Aantal proefpersonen:	3197
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	NL5412
NTR-old	NTR5740
Ander register	WBO : 161536-112008-PG

Resultaten