

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

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23322

Source

NTR

Health condition

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

Sponsors and support

Primary sponsor: Academic Medical Centre
Erasmus Medical Center

Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Participation-rate and diagnostic yield of a 4th round of biennial FIT-screening compared to

previous rounds.

Impact of repeated biennial FIT-screening on participation-rates (per round, in consecutive rounds and per program), as well as the yield and occurrence of interval cancers in participants and non-participants of repeated rounds.

Study description

Background summary

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.

Study objective

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

Study design

n.a.

Intervention

n.a.

Contacts

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Eligibility criteria

Inclusion criteria

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).

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control: N/A , unknown

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 01-03-2014
Enrollment: 20000
Type: Actual

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5278
NTR-old	NTR5385
Other	WBO: 161536-112008-PG : ZonMw: 50-51515-98-302

Study results

Summary results

n.a.