Implementation of population screening for colorectal cancer by repeated Fecal Immunochemical Test (FIT): 3 round.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26636

Source
NTR

Brief title
FITTeR

Health condition

Colorectal cancer, screening, FIT

Sponsors and support

Primary sponsor: Initiator: Academic Medical Centre (AMC), departement of Gastroenterology & Hepatology. Co-centre: Flevoziekenhuis Almere
Source(s) of monetary or material Support: Zon-MW, The Netherlands Organization for Health research and development

Intervention

Outcome measures

Primary outcome

Participation rate.

Secondary outcome

1. Evaluation of the diagnostic yield of FIT;

2. Evaluation of the reasons for non-participation;

3. Evaluation of the interval carcinomas during three subsequent screening rounds.

Study description

Background summary

Colorectal cancer (CRC) is the second most common cancer in the Western world. The lifetime incidence for patients at average risk is about 5 %. Fecal Immunochemical Test (FIT), sigmoidoscopy, colonoscopy and CT-colonography are available options for colorectal cancer screening. FIT and sigmoidoscopy are the only methods with a documented reduction in CRC-related mortality in randomized clinical trials.

FIT is based on the principle of detecting blood in stool that may originate from a bleeding CRC or large adenoma. FIT is frequently used as screening test worldwide because it is simple to perform at home, is non-invasive and relatively cheap. Two main classes of FITs are available: Guiac-FOBT (gFIT) and faecal immunochemical tests (FIT). gFOBT detect any blood in stool whereas FIT is more specific for human haemoglobin. Adenomas and even CRCs usually bleed intermittently and therefore repetitive (biannual) testing is required.

In 2005-2006 a pilot screening program was performed in Amsterdam and Nijmegen. 20.000 individuals were invited and randomized to either guiac-FOBT or FIT-screening. Participation rate was significantly higher in the FIT-group compared to the guaic FOBT group (60% versus 47%). 9% of all participants had a positive test result. The intention-to-screen detection rate for advanced neoplasia favoured FIT (1.4% versus 0.6%).

To be effective, participation to subsequent screening rounds is essential. A 2nd round of FIT-screening started in 2008. In this study, individuals of the Amsterdam cohort (10.000 individuals) were invited to participate in a 2nd round of (FIT) screening. Participation rate of the 2nd round was lower compared to the 1st round (52% versus 57%). This was mainly due to the non-reponders of the 1st round (21%), but also new invitees (48%) contributed to the lower participation rate. 86% of all participants to the 1st round also participated in the 2nd round. Of all participants to the 2nd round, 8% had a positive test result and 88% of them underwent subsequent colonoscopy. Advanced neoplasia was detected in 44% of them. After matching all invitees to the cancer registry, stage of screen-detected CRCs during the 1st and 2nd round was significantly lower compared to the stage of detected CRCs in non-participants.

As program adherence is of utmost importance in biannual FIT screening we evaluate the participation rate of a third round FIT screening in the Netherlands.

The colonoscopies will take place in two centres; the Flevo Hospital in Almere and the Academic Medical Centre in Amsterdam.

Study objective

Evaluation of a population-based screening program for colorectal by repeated Fecal Immunochemical Test (FIT).

Study design

Evaluation of the participation rate: All individuals will be invited for FOBT screening by mail. All individuals will receive a pre-announcement 2 weeks before the actual invitation. All non-participants will receive a reminder 4 weeks after the initial invitation. The participation rate will be reported as the percentage of invited subjects who attended FIT screening.

Evaluation of secondary outcomes:

Ad. 1: Detection rate of all adenomas and carcinomas relative to all invitees and relative to all participants;

Ad. 2: Reply-card send by mail together with the invitation;

Ad. 3: Carcinoma detected in a FIT-negative individual, between the rounds of screening.

Intervention

For this study, 10.000 individuals will be invited for CRC screening by FIT (OC-sensor).

Contacts

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Eligibility criteria

Inclusion criteria

1. Asymptomatic individuals between 50 and 74 years of age;

2. Individuals living in the target area (similar to 1st and 2nd round): Amsterdam, Almere, Watergraafsmeer and Diemen;

3. Non-responders to the 1st and/or 2nd round;

4. Responders to 1st and/or 2nd round;

5. First-time invitees (persons aged 50–75 that moved into the target area or persons that turned 50 within the last 2 years).

Exclusion criteria

1. FIT positive in 1st or 2nd round;

2. Complete colonoscopy or CT colonography performed within the last 2 years;

3. Personal history of colorectal cancer;

4. Severe co-morbidity (ASA IV/V);

5. Terminal disease (life-expectancy < 5 years);

6. Inability or refusal to provide informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2011
Enrollment:	10000
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-02-2011
Application type:	First submission

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	NL2626
NTR-old	NTR2755
Other	WBO : PG/ZP 2.642.467
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A