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

No registrations found.

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

Summary

ID

NL-OMON26021

Source
Nationaal Trial Register

Brief title
Vergelijkende studie

Health condition

screening, colorectal cancer

Sponsors and support

Primary sponsor: Erasmus Medical Centre
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

detection rate of advanced neoplasia

Secondary outcome

Participation, positivity rate, diagnostic yield of FIT screening, relative sensitivity.

Study description

Background summary

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.

Study design

n.a.

Intervention

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

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-05-2016
Enrollment:	44038
Type:	Anticipated

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	NL5721
NTR-old	NTR5874
Other	: 769500-135716-pg

Study results