Immunochemical FOBT screening for colorectal cancer: yield and attendance for one- versus two-sample tests, and for second round screening with various intervals.

No registrations found.

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

Summary

ID

NL-OMON26711

Source
Nationaal Trial Register

Brief title
CORERO-II

Health condition

Colorectal cancer

Sponsors and support

Primary sponsor: Erasmus Medical Center, Rotterdam
Department of Gastroenterology and Hepatology
Source(s) of monetary or material Support: ZonMw, The Netherlands Organization for Health Research and Development, KWF Kankerbestrijding

Intervention

Outcome measures

Primary outcome

Adherence for second round CRC screening with 1-sample iFOBT (OC-Hemodia Latex) comparing annual, biennial, and triennial screening interval.

Adherence and diagnostic yield of a first screening round comparing 1-sample versus 2-sample iFOBT screening.

Secondary outcome

The diagnostic yield of the various intervals of a second round iFOBT screening.
The feasibility and required colonoscopy capacity needed for further evaluation of participants with a positive iFOBT screening.
Side effects of screening.

Participants' experiences; the acceptability, satisfaction and burden of screening in different rounds and use of one or two-sample iFOBT.

Reasons for non-participation.

The cost-effectiveness ratio of the three different screenings-intervals and the one and two-sample iFOBT.

Study description

Background summary

CRC fullfils the screening and surveillance criteria of Wilson and Jungner, i.e. the disease poses an important health problem with significant morbidity and mortality, the disease has a clearly detectable and treatable precursor, and early detection of CRC improves the prognosis (even dramatically in case non-cancerous precursor adenomas are detected and treated). For these reasons, screening for CRC has already started in various countries. There is no doubt about the importance of evaluating screening
for CRC in the Netherlands. In 2001, the National Health Council advised the Ministry of Health, Welfare and Sport to consider the implementation of CRC screening, and to study the prerequisites for such implementation. The most effective screening strategy for CRC is still under debate. The national colorectal carcinoma screening investigation group (COCAST workgroup) therefore advised to study implementation and participation of two different FOBT screening
methods. Hence, Amsterdam/ Nijmegen and our group (Rotterdam) recently performed a study directly comparing implementation, participation, and diagnostic yield of gFOBT (Haemoccult II) and iFOBT (Hemodia-latex). Preliminary results of these studies show a

significantly higher adherence and diagnostic yield for the iFOBT compared to the gFOBT. Final results are expected in April 2008.
Moreover, if iFOBT screening is to be implemented, repeated rounds will be necessary given the low sensitivity of the tests for early neoplastic lesions. However, data on adherence and diagnostic yield of
repeated iFOBT screening are lacking. For that purpose, data on adherence and diagnostic yield of repeated FOBT screening are needed before starting a nationwide iFOBT screening program. These data need to be related to a search for the optimal screening interval, which is also unknown. Our study will provide important data on adherence and diagnostic yield of a successive round of iFOBT screening
after one (annual), two (biennial) or three (triennial) years.

The two Dutch feasibility studies used one-sample iFOBT screening. Two other studies have demonstrated an increased sensitivity and cost-effectiveness of two-sample iFOBT screening. Therefore data on the adherence and diagnostic yield of two-sample iFOBT screening in The Netherlands are needed. Internationally, this is the first study that directly compares diagnostic yield and
adherence of one- and two-stool sample iFOBT screening. Furthermore, the data of second round screening with various intervals and screening with one versus
two sample iFOBT will also allow a cost-effectiveness analysis, showing the tradeoff between adherence, yield and costs between screening strategies. Participants' satisfaction and burden, as well as reasons for non-attending will be determined. These data are essential to optimize a nationwide
screening for CRC. Therefore, the above mentioned research questions were also determined as key-issues that should be high on the Dutch ZonMw research list in order to determine the optimal screening strategy for a national CRC screening program in The Netherlands.

Study objective

The primary objective of the study is to determine:

• Adherence for second round CRC screening with one-sample iFOBT (OC-Hemodia Latex) comparing
annual, biennial, and triennial screening interval.

• Adherence and diagnostic yield of a first screening round comparing one-sample versus two-sample iFOBT screening.

Study design

- Start: 01-05-2008

- Interim analysis: none

- End: 31-12-2010

Intervention

1-sample or 2-samples immunochemical FOBTs.

Firstly, a representative population sample of 2.500 asymptomatic persons between 50-75 years of age in the region ‘Rijnmond’ will be invited for the 1st screening round using 1-sample iFOBT in 2008 and for a 2nd screening round after one year (group A).

Secondly, the 5.000 asymptomatic persons who were invited in our first trial for a 1st-round one-sample iFOBT in 2006/2007 (NTR = 1096), will be invited for 2nd round screening. They will be pre-randomized for biennial (group B) or triennial (group C) 2nd round screening. The attendance rate of these two groups will be compared with the participation of the second screening round from group A.

Furthermore, 3.200 newly randomly selected persons will be invited for a single 1st round screening using 2-sample iFOBT (group D). The attendance rate of this group will be compared with the participation of the first screening round from group A.

Contacts

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Eligibility criteria

Inclusion criteria

1. Asymptomatic individuals aged 50-75 years old, who are able to provide an informed consent.

Exclusion criteria

1. Inability or refusal to provide informed consent

2. History of CRC or inflammatory bowel disease

3. Severe or terminal disease, life expectancy less than 5 years

4. Colonoscopy, sigmoidoscopy or contrast barium enema within the previous three years

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2008
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-10-2008
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	NL1451
NTR-old	NTR1512
Other	ZonMw : 505011596518
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A