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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26711

Bron
Nationaal Trial Register

Verkorte titel
CORERO-II

Aandoening

Colorectal cancer

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Rotterdam
Department of Gastroenterology and Hepatology
Overige ondersteuning: ZonMw, The Netherlands Organization for Health Research and Development, KWF Kankerbestrijding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

- Start: 01-05-2008

- Interim analysis: none

- End: 31-12-2010

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2008
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-10-2008
Soort:	Eerste indiening

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	NL1451
NTR-old	NTR1512
Ander register	ZonMw : 505011596518
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A