Implementation of Colorectal Cancer Screening with FOBT in the Netherlands.

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Implementation of Colorectal Cancer Screening with FOBT in the Netherlands is feasible

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

Samenvatting

ID

NL-OMON20383

Bron
NTR

Verkorte titel
FOCUS

Aandoening

Mass Screening, Occult Bleeding, Response Rate, Colorectal Cancer

Ondersteuning

Primaire sponsor: Department of Gastroenterology and Hepatology, 455 University Nijmegen Medical Centre Radboud
Overige ondersteuning: The Netherlands Organisation for Health Research and Development (ZonMw)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Response rate per FOBT

Toelichting onderzoek

Achtergrond van het onderzoek

Colorectal cancer (CRC) morbidity and mortality generates a major health problem. CRC morbidity and mortality can be reduced by screening and should be implemented according to the European Community. At present evidence indicates that fecal occult blood testing is the screening method of choice, but many issues essential to a well organized screening program are still unanswered. One of the major concerns is the sometimes extremely low response to, and compliance rate of CRC screening programs in many countries. The primary aim of this study is to assess the response to the screening protocol under different conditions. In addition it will be examined how response to the screening protocol can be optimized. Furthermore, feasibility and organizational logistics and some cost-effectiveness issues of CRC screening will be investigated.

A representative sample of the Dutch population consisting of 20,000 asymptomatic average risk subjects in the age-group of 50-74 years, from the Nijmegen and Amsterdam area, will be invited to participate. All prospective subjects will receive a general information leaflet about CRC-screening, a risk assessment questionnaire and a FOBT. The subjects will be randomized to receive either a FOBT-kit based on a guaiac or an immunochemical testing method. If the FOBT turns out to be positive or the questionnaire indicates an elevated risk, subjects will be invited for colonoscopy. Each subject will also receive a questionnaire to study quality of life. Reasons for non-response will finally be evaluated by a telephone questionnaire.

The project will be implemented in screening centers affiliated to University Medical Center Nijmegen (UMCN) and to Amsterdam University Medical Center (AMC), in collaboration with the Comprehensive Cancer Centers in Nijmegen (IKO) and Amsterdam (IKA).

The results will facilitate the decision whether or not to implement nation-wide CRC screening in the Netherlands. In the light of our previous and current commitment and investments, we are obliged to participate in future extensions of the study, for example extension of the FOBT-screening method with other procedures, such as sigmoidoscopy, colonoscopy, double-contrast barium enema or CT-colonography.

Doel van het onderzoek

Implementation of Colorectal Cancer Screening with FOBT in the Netherlands is feasible

Onderzoeksproduct en/of interventie

1. Invitation by information of municipal database versus general practioner database
2. Fecal Occult Blood Test (FOBT)
Guaiac-FOBT versus Immunochemical FOBT one day or two day testing
3. If FOBT positive: Colonoscopy

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Men and women 50-75 years of age

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Living in an institution or similar

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2006
Aantal proefpersonen:	20000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-06-2007
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	NL982
NTR-old	NTR1006

Register	ID
Ander register	: CRC01
ISRCTN	ISRCTN57917442

Resultaten