Population screening for colorectal cancer by colonoscopy or CT-colonography in the Netherlands.

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Evaluation of a population-based screening program for colorectal cancer in the Netherlands by direct colonoscopy or CT-colonography.

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

Samenvatting

ID

NL-OMON24258

Bron
Nationaal Trial Register

Verkorte titel
CoCoS

Aandoening

Colorectal cancer, adenomatous polyps, screening, colonoscopy, CT-colonography

Ondersteuning

Primaire sponsor: Primary initiators: Academic Medical Center (AMC) and Erasmus Medical Center, Department of Gastroenterology & Hepatology and department of Radiology.
Overige ondersteuning: Primary sponsor: ZON-MW, The Netherlands Organization for Health Research and Development
Secondary sponsor: Center for Translational Molecular Medicine (CTMM)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Evaluation of the participation rate of a population-based screening program by colonoscopy or CT-colonography in the Netherlands.

Toelichting onderzoek

Achtergrond van het onderzoek

Colorectal cancer (CRC) is a lethal disease and the second most common cancer in the Western world. The lifetime incidence for patients at average risk is about 5 %. Fecal occult blood tests (FOBT), sigmoidoscopy, colonoscopy and CT-colonography are available options for colorectal cancer screening, with FOBT being the only one with a documented reduction in CRC-mortality in randomized clinical trials.

Colonoscopy is the current reference standard for the detection of colorectal cancer and its precursor lesions, adenomas. Population screening by colonoscopy should not only reduce both CRC morbidity and mortality, but also its incidence by removing its precursor lesions. CT-colonography is another option for CRC screening. CT-colonography comprises a full colon examination after carbon dioxide insufflation with comparable accuracy for advanced adenomas. In case of polyps ¡Ý 10 mm, a colonoscopy will follow for confirmation and therapy.
The participation rate is a crucial factor in the effectiveness of a screening program. As colonoscopy is an invasive procedure with a burdensome preparation procedure and a risk of complications, it is uncertain how many people will accept a screening offer for colonoscopy. Possibly, preliminary interview by phone instead of a preliminary interview at the outpatient clinic will increase the participation rate. The CT-colonography procedure with limited bowel preparation could be a preferable alternative in a screening setting.
It is unknown to what extent people invited to a screening program based on CT-colonography or colonoscopy will participate.

In this proposal we aim to compare the participation rate of direct colonoscopy and CT-colonography CRC-screening in the Dutch population. The study will be performed and analysed in the Academic Medical Centre and Erasmus Medical Centre, in close collaboration with the regional Comprehensive Cancer Centres. We intend to invite 7500 persons aged 50-75 years in the Amsterdam and Rotterdam region randomized (1:1:1) for direct colonoscopy and preliminary interview by phone, direct colonoscopy and preliminary interview at the outpatient clinic and CT-colonography (preliminary interview by phone). If

there are no contra-indications and informed consent is obtained, they will be planned for the procedure in one of the two screening centres. Outcomes and quality control of the procedures are systematically measured.

The primary outcome parameter is the participation rate of direct colonoscopy and CT-colonography. In addition, we will evaluate the yield, quality, complications, level of informed-choice, burden and feasibility of CRC-screening with these methods. Validated questionnaires, provided at different moments, will measure patients' experience with the screening programme. Furthermore, a structured biobank with stool, blood and colonic tissue collection of all patients at colonoscopy will be initiated to facilitate future development of molecular screening tests for CRC. We will incorporate the final results of this study in the validated MISCAN-colon screening model for cost-effectiveness of different methods of CRC screening in our country.

The results of this study will enable an evidence-based comparison of CRC-screening by colonoscopy and CT-colonography in the Netherlands.

Doel van het onderzoek

Evaluation of a population-based screening program for colorectal cancer in the Netherlands by direct colonoscopy or CT-colonography.

Onderzoeksopzet

Evaluation of the participation rate:
All individuals will be invited for direct colonoscopy or CT-colonography screening for CRC by mail. All non-participants will receive a reminder 4 weeks after the invitation. The participation rate will be reported as the percentage of invited subjects who attended colonoscopy or CT-colonography.

Evaluation of secondary outcomes:

Ad. 1: evaluation of factors influencing participation and patients' experience with the screening programme. Knowledge and awareness of CRC, the level of informed choice in the decision-making process and the burden of colonoscopy and CT-colonography (expected and perceived) will be documented. All results will be compared with the results of the ongoing Dutch implementation studies on FOBT and sigmoidoscopy screening. Furthermore, the results will be incorporated in the validated MISCAN screening model for cost-effectiveness of different methods of CRC screening in the Netherlands.

Ad. 2: all procedures will be performed according to a list of quality guidelines. All

complications will be documented in a database.

Ad. 3: detection rate of all adenomas and carcinomas in the individuals who attended colonoscopy or CT-colonography.
Ad. 4, 7 and 8: baseline questionnaire send by mail prior to colonoscopy/CT-colonography. This questionnaire is based on previous CRC screening studies performed in AMC and Erasmus MC (ZonMW-implementation 6300.004 + 120710007)

Ad. 5: burden questionnaire send by mail after performing colonoscopy/CT-colonography. This questionnaire is based on previous CRC screening studies performed in AMC and Erasmus MC (ZonMW-implementation 6300.004 + 120710007)

Ad. 6: baseline questionnaire send by mail prior to colonoscopy and a (non-participation) questionnaire asked by phone to 10 % of the individuals who did not respond after 2 months.

Ad. 9: a diary will be filled in by participants to evaluate real time investment.

Ad. 10: all results will be incorporated in the validated MISCAN screening model.

Onderzoeksproduct en/of interventie

For this study, 7500 persons will be invited and randomized (1:1:1) in three different arms:

1. CT-colonography (2500 individuals);

2. Colonoscopy and preliminary interview by phone (2500 individuals);

3. Colonoscopy and preliminary interview at outpatient clinic (2500 individuals).

Furthermore, an extra number of 10.000 persons will be randomized for the NORDICC trial (this trial will be registered separately). These persons will not be invited to participate in the screening program.

The primary outcome of this study is the participation rate. The expected participation rate for the respective separate arms is 35 %, 27,5 % and 22,5 %. Consequently, a total number of 1250 colonoscopies and 875 CT-colonographies is expected.

To allow sufficient certainty, we will continue the study until the target number of 1250 colonoscopies and 875 CT-colonographies is reached.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

2. Individuals living in pre-selected postal areas in Amsterdam and Rijnmond region.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Participants in previous CRC population screening trials;

2. Complete colonoscopy performed within the last 5 years;

3. Personal history of colonic adenomas or colorectal cancer;

4. Longstanding IBD;

5. Severe or terminal disease (life-expectancy < 5 years);

6. Inability or refusal to provide informed consent.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2009
Aantal proefpersonen:	7500
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	25-05-2009
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	NL1719
NTR-old	NTR1829
Ander register	ZonMw numbers / 2009/03WBO : 121010007 and 170720012 / WBO-number
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A