The efficacy of cap-assisted colonoscopy compared with regular colonoscopy in CRC screening participants.

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Cap-assisted colonoscopy may improve the adenoma detection rate in CRC screening participants.

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

Samenvatting

ID

NL-OMON29640

Bron
NTR

Verkorte titel
CACOS

Aandoening

adenoma, cap-assisted colonoscopy

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC) and Erasmus Medical Center, Departments of Gastroenterology & Hepatology
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

1. Percentage of patients with adenomas detected with cap-assisted colonoscopy compared to regular colonoscopy;

2. Adenoma detection rate of cap-assisted colonoscopy compared to regular colonoscopy.

Toelichting onderzoek

Achtergrond van het onderzoek

Colorectal cancer (CRC) is the second most prevalent type of cancer and an important cause of death in the Netherlands. Reduction of the incidence of CRC can be achieved by detection and removal of its precursor lesions, adenomas. In 2005, the Dutch Health Council advised to investigate the implementation of different population screening methods for CRC in the Netherlands. Colonoscopy is widely accepted as the gold standard for detection of colorectal neoplasia. However, a substantial adenoma miss rate of 20-26 % has been reported in tandem colonoscopy studies. This may be due to adenomas situated outside the visual field, either hidden behind folds or at flexures. The use of a transparent hood (“cap-assisted colonoscopy”) could be helpful in detecting and removing colorectal polyps by depressing semilunar folds during inspection. Several studies with drawbacks in study-design failed to demonstrate that cap-assisted colonoscopy increases the adenoma detection rate. If adenoma detection rates are higher in cap-assisted colonoscopy, this would result in a higher yield of CRC screening by colonoscopy and thus lower the incidence of CRC.
In this proposal we aim to compare adenoma– and polyp detection rate in cap-assisted colonoscopy compared with regular colonoscopy in screening participants for CRC. Furthermore, we will analyze the cecal intubation time, polypectomy time, difficulty of different colonoscopic procedures, burden of colonoscopies and complication rates.

All participants will be randomized (1:1) for cap-assisted colonoscopy or regular colonoscopy. The study will be facilitated by the logistic backbone of the screening program for CRC.

Doel van het onderzoek

Cap-assisted colonoscopy may improve the adenoma detection rate in CRC screening participants.

Onderzoeksopzet

All individuals planned for CRC screening by direct colonoscopy, will be asked to participate in this study. After obtaining informed consent, colonoscopy will be performed within 4 weeks in one of the two participating centres by professionals with an experience of at least 200

regular and 20 cap-assisted colonoscopies. The colonoscopy will be performed taking the standard quality aspects into account. When performing cap-assisted colonoscopy, a transparent hood is attached at the tip of a cap-fitted colonoscope so that the tip of the hood was 4 mm ahead of the edge of the colonoscope. A side hole on the distal attachment is added to drain fluid during observation and procedure allowing clear endoscopic view. Time to reach the cecum and withdrawal time will be measured by using a stopwatch. Withdrawal time will be at least 6 minutes. Polypectomy time will be calculated by recording the time when passing an instrument through the instrument channel for polypectomy and the time when the polyp has been removed. Of all detected lesions the size, morphology (sessile, pedunculated, flat or depressed), localization and the macroscopic aspect will be noted. All detected lesions will be removed during the same procedure if possible. If immediate endoscopic treatment is impossible, biopsies will be obtained and pathological assessment of these tissue samples will provide a definitive diagnosis. Histology will be processed and stained using standard methods and will be evaluated by expert pathologists. Histology will be defined according to the Vienna criteria. Dysplasia will be defined as either low grade or high grade and all polyps will be classified into hyperplastic, tubular, tubulovillous and villous lesion.
The endoscopist will be asked to asses the difficulty of the polypectomy procedure (in case of polyps > 5 mm), the whole colonoscopic procedure, retroflexion in the lower rectum and ileum intubation by using a 5-points scale.
The burden of colonoscopy will be evaluated by a validated questionnaire, which is part of the screening program for CRC. All complications will be registered in a database until 30 days after colonoscopy.

Onderzoeksproduct en/of interventie

For this study, all individuals who participate in the pilot study for populationscreening for CRC by direct colonoscopy will be randomized in two different arms:

1. Cap-assisted colonoscopy;

2. Regular colonoscopy.

A total number of 5000 individuals will be invited for our screening program. We expect a participation rate of 25 %, resulting in 1250 participants, 625 individuals in each arm.
The primary outcome of this study is the adenoma detection rate. The study size sample was calculated to be 493 patients. To allow sufficient certainty, the whole group participating in colonoscopy screening will be included in the trial (625 colonoscopies in each arm is expected).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Asymptomatic individuals between 50 and 74 years of age, undergoing scheduled screening colonoscopy;

2. Written informed consent.

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:	03-07-2009
Aantal proefpersonen:	1250
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	30-06-2009
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	NL1778
NTR-old	NTR1888
Ander register	WBO number: 2009/03WBO : ZonMW number: 170720012
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A