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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29640

Source
NTR

Brief title
CACOS

Health condition

adenoma, cap-assisted colonoscopy

Sponsors and support

Primary sponsor: Academic Medical Center (AMC) and Erasmus Medical Center, Departments of Gastroenterology & Hepatology
Source(s) of monetary or material Support: Primary sponsor: ZON-MW, The Netherlands Organization for Health Research and Development

Secondary sponsor: Center for Translational Molecular Medicine (CTMM)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

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

2. Polyp detection rate of cap-assisted colonoscopy compared with regular colonoscopy;

3. Cecal intubation times and rates in cap-assisted colonoscopy compared to regular colonoscopy;

4. Polypectomy time of cap-assisted colonoscopy compared to regular colonoscopy;

5. Difficulty of the colonoscopy and polypectomy procedure in cap-assisted colonoscopy compared to regular colonoscopy;

6. The burden of colonoscopy in cap-assisted colonoscopy compared to regular colonoscopy;

7. Complication rates of cap-assisted colonoscopy and regular colonoscopy;

Study description

Background summary

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.

Study objective

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

Study design

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.

Intervention

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).

Contacts

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Eligibility criteria

Inclusion criteria

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

2. Written informed consent.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-07-2009
Enrollment:	1250
Type:	Actual

Ethics review

Positive opinion

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

Study results

Summary results
N/A