Comparison of adenoma miss rate and adenoma detection rates between Endocuff Vission-assisted colonoscopy and conventional colonoscopy: a multicenter randomized trial (EXCEED study)

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(1) To compare adenoma miss rates (AMR) between Endocuff Vision-assisted colonoscopy (EAC) and conventionalcolonoscopy (CC)(2) To compare adenoma detection rates (ADR) between EAC and CC(3) To assess whether a proposed increased ADR and reduced AMR...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON44323

Source
ToetsingOnline

Brief title
EXCEED study

Condition

- Gastrointestinal conditions NEC

Synonym
colorectal cancer, polyps

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Norgine

Intervention

Keyword: adenoma, colonoscopy, endocuff, polyp

Outcome measures

Primary outcome

Adenoma miss rate

Secondary outcome

Secondary endpoints include; ADR, mean number of adenomas detected per colonoscopy procedure, number of sessile serrated polyps, the total number of colon lesions found during the first and second examination (which will be compared for size, colon distribution, morphologic and histopathological characteristics), cecal intubation rates, bowel cleansing levels, procedure times, sedation use, (severe) adverse events, patient reported outcome (pain, World Health Organisation performance status), and post-colonoscopy surveillance intervals applying European and United states surveillance guidelines.

Study description

Background summary

Population screening programs for colorectal cancers (CRC) are increasingly adapted as a public health initiative with the primary goal to prevent CRC and CRC related deaths. The ultimate benefit of CRC screening relies on the detection and resection of (pre-)malignant colon lesions, and for this colonoscopy is the preferred modality. Recently, concerns have been raised about the effectiveness of colonoscopy in the prevention of CRC after several studies reported unexpected high incidence rates of interval carcinomas (IC), especially in the proximal colon.[5-9] Most ICs are suspected to arise from missed colon lesions during colonoscopy. The retrograde approach of colonic inspections may contribute to colon lesions remaining undetected as it limits visualization of the proximal sides of haustral folds and flexures. Endocuff Vision is a single-use, disposable medical device designed to improve the detection of colon lesions. The 'finger-like' projections of the device provide fold retraction allowing the visualization of otherwise hidden anatomical areas. Additionally, Endocuff Vision may improve scope tip stability and prevent scope slippage.
The present study will be the first study to compare adenoma miss rates (AMR) and ADR between Endocuff Vision-assisted colonoscopy (EAC) and conventional colonoscopy (CC) in non-IFOBT based colonoscopy patients.
Additionally, this study will evaluate whether a proposed increased ADR and reduced AMR with EAC is indeed due to the accessory device or merely a consequence of the second colonoscopy procedure performed.

Study objective

(1) To compare adenoma miss rates (AMR) between Endocuff Vision-assisted colonoscopy (EAC) and conventional colonoscopy (CC)
(2) To compare adenoma detection rates (ADR) between EAC and CC
(3) To assess whether a proposed increased ADR and reduced AMR with EAC is indeed due to the fold-flattening device or merely a consequence of the second colonoscopy procedure performed.
(4) To assess the clinical relevance of the polyps missed during the first colonoscopy procedure.

Study design

This multicenter randomized, same-day, back-to-back tandem colonoscopy trial will include four separate study groups: group A; CC followed by CC, Group B; CC followed by EAC, Group C; EAC followed

by CC, and group D; EAC
followed by EAC.

Intervention

Endocuff Vision- assisted colonoscopy

Study burden and risks

Colonoscopy is a commonly performed procedure and the overall serious adverse event (SAE) rate is low, around 2.8
per 1000 colonoscopies. The risk of adverse events (AE) for EAC are believed to be equivalent to CC, including
bleeding and perforation risks. Patients burden will consist of two follow-up telephone calls to assess patients reported
outcome and adverse events. Additionally, general colonoscopy related risk may increase in a repeated colonoscopy
trial. A very important benefit for participating subjects relies in a more thorough investigation of the colon. Repeated
colonoscopy has been shown to result in the detection of more neoplastic colon lesions, which has been inversely
related to the risk of developing interval carcinomas.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

aged between 40-75
referred for screening (non-IFOBT based), diagnostic or surveillance colonoscopy

Exclusion criteria

- Prior surgical resection of any portion of the colon or a history of radiotherapy for any abdominal or pelvic disease
- Personal history of colon cancer or polyposis syndrome
- Familial adenomatous polyposis (FAP)
- Known colitis or suspicion of colitis
- Lower gastro-intestinal bleeding requiring acute intervention
- Suspicion of large bowel obstruction or toxic megacolon
- Prior incomplete colonsocopy (not including insufficient preparation)
- ASA >3

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2017
Enrollment:	708
Type:	Actual

Medical products/devices used

Generic name:	Endocuff Vision
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	23-01-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
CCMO	NL61925.056.17