

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

Published: 23-01-2018

Last updated: 12-04-2024

(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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Gastrointestinal conditions NEC
<b>Study type</b>	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**

### **Public**

Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 8  
Nijmegen 6525GA  
NL

### **Scientific**

Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 8  
Nijmegen 6525GA  
NL

## **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 colonoscopy (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