# Colonoscopy with EndoCuff vs conventional colonoscopy A randomized controlled trial

Published: 17-04-2013
Last updated: 24-04-2024

We aim to test the hypothesis that EndoCuff improves totaal number of adenomas detected and ADR compared with regular colonoscopy. In other words, we'll study if the Endocuff colonoscopy detects more polyps.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Malignant and unspecified neoplasms gastrointestinal NEC |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON39964

**Source**
ToetsingOnline

**Brief title**
EndoCuff trial

### Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms benign

**Synonym**
colonic polyp, colorectal adenoma, precursor coloncancer

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Stichting Procolo, centrum voor dikkedarmonderzoek
**Source(s) of monetary or material Support:** ARC Endocuff (bedrijf uit UK dat device

ontwikkeld heeft)

## Intervention

**Keyword:** adenoma detection rate, colon carcinoma, colonoscopy, Endocuff

## Outcome measures

### Primary outcome

Mean number of adenomas per patient

Adenoma detection rate (percentage of colonoscopies where at least one adenoma

is found)

### Secondary outcome

* Polyp detection rate & number of polyps per patient

* Flat adenoma detection rate

* Polyp retrieval rate

* Cecal intubation rate and cecal intubation time

* Discomfort during the procedure using the Gloucester Comfort scale

* Subjective difficulty of the procedure as assessed by the endoscopist

* Complication rate

# Study description

### Background summary

Colonoscopy is the current reference standard for detection of colorectal cancer (CRC) and its precursor lesions, adenomas. Several tandem studies have reported a substantial adenoma miss rate of 20-26%, and approximately 2-12% for polyps larger than 10mm. Recently a landmark paper was published, that demonstrated that patients that underwent a screening colonoscopy performed by an endoscopist with an adenoma detection rate (ADR) of greater than 20% had a significantly lower chance of developing an interval carcinoma than when scoped by an endoscopist with an ADR lower than 20%. However, an ADR of 20% is not

always accomplished.
ADR has an inherent limitation as it does not measure the total number of adenomas detected. Within the British NHS Bowel Cancer Screening program (BCPS), the mean number of adenomas per procedure (MAP, total number of adenomas detected divided by the number of procedures) was assessed, besides the ADR. In the BCPS, MAP was 0.91 in FOBT-positives, whereas in symptomatic populations MAP is around 0.7.

There are several reasons for missing colonic lesions, including the anatomical location of polyps on the proximal side of the folds. One of the inventions aimed at visualizing the proximal surface of the mucosal folds in an effort to reduce polyp miss rates is a transparent plastic cap that is placed at the tip of the endoscope. The results of studies comparing cap-assisted colonoscopy with conventional colonoscopy are however variable. Our study group compared conventional colonoscopy and cap-assisted colonoscopy in a large randomized study in an average-risk population and demonstrated no statistical difference in the ADR between both groups, nor in MAP. We hypothesized that maneuvering the colonoscope with the cap to each fold, takes a lot of effort for the colonoscopist. In a large study (approximating daily practice) this may not be done consequently.
If a cap would be able to straighten colonic folds without blurring the endoscopic view this could possibly increase detection of polyps on the proximal side of folds and increase the total number of adenomas detected. Recently, a cap was developed which aims to do so, the EndoCuff. This special cap has two circular rows of plastic hairs that, when pulling the scope back, should distend the folds, prevent slippages of the mucosa and improve tip control. Besides this potential advantage, EndoCuff could possibly also facilitate cecal intubation by facilitating straightening of the endoscope during intubation and prevention of looping. Clinical studies using EndoCuff have not been performed yet.

## Study objective

We aim to test the hypothesis that EndoCuff improves totaal number of adenomas detected and ADR compared with regular colonoscopy. In other words, we'll study if the Endocuff colonoscopy detects more polyps.

## Study design

Multicenter, open randomized, controlled trial

## Study burden and risks

Not applicable

# Contacts

**Public**
Stichting Procolo, centrum voor dikkedarmonderzoek

Meibergdreef 9
Amsterdam 1105 AZ
NL
**Scientific**
Stichting Procolo, centrum voor dikkedarmonderzoek

Meibergdreef 9
Amsterdam 1105 AZ
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

*Aged 45 years and older
*Scheduled for colonoscopy for on of the following indications: polyp surveillance, changed bowel habits and/or bloody stools or bowel complaints, FOBT+ screening, positive family history for CRC, abdominal pain
*Signed written informed consent
*ASA class I, II or III

## Exclusion criteria

*Polyposis syndromes
*Inflammatory bowel disease (active disease or surveillance)

*Previous partial colonic resection
*Known conditions that require the use of a paediatric colonoscope (severe diverticulosis or abdominal surgery in the medical history)
*Colonoscopy after polyp detection with CT-colonography
*Known colonic stricture
*Any acute indication for colonoscopy

# Study design

## Design

| | |
|---|---|
| Study type: | Observational invasive |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Diagnostic |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 19-08-2013 |
| Enrollment: | 1058 |
| Type: | Actual |

# Ethics review

| | |
|---|---|
| Approved WMO Date: | 17-04-2013 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 03-05-2013 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

| | |
|---|---|
| Approved WMO Date: | 15-04-2014 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 08-09-2014 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 23-10-2014 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 10-12-2014 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

# 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 | NL42327.018.13 |