Complete polyp resection rate of colorectal polyps: long follow-up study

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To compare the percentage of incompletely resected polyps during colonoscopy for polyps sized 1-4 mm, 5-9 or 10-20 mm.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Benign neoplasms gastrointestinal
Study type	Observational invasive

Summary

ID

NL-OMON40330

Source
ToetsingOnline

Brief title
CLEAR study: CompLEte polyp removAl Rate

Condition

- Benign neoplasms gastrointestinal

Synonym
incompletely removed polyp

Research involving
Human

Sponsors and support

Primary sponsor: MDL
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: colonoscopy, colorectal polyp, resection, screening

Outcome measures

Primary outcome

Percentage of incompletely resected polyps with a diameter of 1-4 mm, 5-9 and

10-20 mm (incomplete resection rate = IRR)

Secondary outcome

* Association between histopathology and IRR

* Association between method of polypectomy and IRR

* Association between polyp morphology according to the Paris classification

and IRR

* Association between polyp location in the colon (proximal vs. distal and per

segment) and IRR

* Association between endoscopist and IRR

Study description

Background summary

In recent years several studies have been published about colorectal interval carcinomas, carcinomas that develop in patients who have had colonoscopic surveillance. Three major causes for interval carcinomas have been described. In 50-80% of the cases, interval carcinomas result from missed lesions at previous colonoscopy. Several tandem studies have reported a substantial adenoma miss rate of 20-26%, and approximately 2-12% for polyps larger than 10mm.Another cause of interval cancers could be that these carcinomas have an aggressive biologic behaviour, for example the association with microsatellite instability.
A third cause of interval colon carcinomas are incompletely removed lesions. These manifest as cancers that arise at the site of the colon where during previous colonoscopy a polyp was resected. Only a small number of studies have evaluated the incidence of interval cancers caused by incomplete resection, with percentages varying from 10-27%. Farrar et al found a significant association between the location of the polypectomy sites within a segment and the subsequent location of the interval carcinoma. However it is hard to draw

strong conclusions about the subject because of the small size of studies on the subject. Besides that, it is difficult to determine whether a cancer occurs at the site of a previously identified premalignant lesion or whether it merely occurred in the same colon segment because of limited descriptive information on adenoma location in colonoscopy reports. Carcinomas arising from incompletely resected polyps highlights the deficiencies in technique and adequate assessment of resection margins. Especially large adenomas that require piecemeal resection are a high risk for incomplete resection. Given the major consequences for patients of failed detection or inadequate removal of neoplastic lesions, systematic evaluation of cancer occurrence after colonoscopy seems the best way to improve patient outcome. However, this can only be studied retrospectively, after the interval carcinoma already developed. A better way to discover the true adequacy of radicality in polypectomy is to directly examine the polypectomy site.
Few studies have evaluated the presence of residual adenomatous tissue by histological assessment of forceps biopsies obtained from the polypectomy site. Complete resection rates vary between different polypectomy techniques, from 40% with cold biopsy forceps to almost 90% with snare polypectomy. A recent study from Pohl et al described an overall incomplete resection rate of 10%, which increased for large polyps and for sessile serrated adenomas/polyps. One great disadvantage of the study method used in these studies, is the bias created by the endoscopist obtaining biopsies from his own polypectomy site. Ideally these biopsies would be obtained by a different endoscopist or during follow-up colonoscopy after the surveillance interval. Also, participating endoscopists were aware of the study design and are could be more focused to ensure complete resections of the polyps.
We aim to test the incomplete resection rate of polypectomies in patients during surveillance colonoscopy after previous polypectomy, and we will compare this rate for different sized polyps.

Study objective

To compare the percentage of incompletely resected polyps during colonoscopy for polyps sized 1-4 mm, 5-9 or 10-20 mm.

Study design

Screening participants with a positive FIT and symptomatic patients between the age of 50-75 years will undergo a colonoscopy. During colonoscopy all detected polyps will be removed as usuall, but only one polyp per segment will be included: the most proximal polyp per segment. Contra lateral of the polypectomy site a single tattoo will be placed to locate the polypectomy site. Per colonic segment only 1 tattoo will be placed, regardless of the number of polyps per segment. After 1, 3 or 5 years, depending on the advised surveillance interval according to the Dutch gastroenterology guidelines, patients will receive a surveillance colonoscopy. The location of previous

polypectomy will be detected with help of the tattoo. If a residual polyp is found, treatment as usual will be performed. If no optical residual is found, several biopsies will be taken at the polypectomy site. Histopathological evaluation of the residual polyp will be compared with previous histopathology. Histopathological evaluation of the biopsies will show if the polypectomy at initial colonoscopy was complete or that microscopic residual polypoid tissue was found.

Study burden and risks

Patients in our study will receive 1 to max.3 tattoos in the colon. The ink we will use (SPOT) for marking the polypectomy site, has been used for many years in colonoscopy practice.1 No side-effects of SPOT have been described in the literature, in contrast to the earlier used ink.1 Patients with suspected colorectal cancers diagnosed during colonoscopy will be excluded from the study and no tattoos for the purpose of the study will be placed. If a tumour is not seen during intubation and a polyp has been removed and marked proximally but a tumour is unexpectedly found distal of the polyp, the patient will be excluded. Because the patient has now two markings of the colon, correct location of the tumour during surgery might be difficult. Because of this risk, we will extensively describe both tattoos and tumour localization with added endoscopic images. We will also personally inform the surgeon.
Patients will be under close surveillance and from multiple studies we know that occurrence of colorectal cancer in a surveillance population is small. During the surveillance colonoscopies biopsies of the former polypectomy site will be taken. In every case colonic biopsies are accompanied by a minimal risk of perforation, bleeding and infection. These complications are cited in the written patient information.

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

FIT positive patients from our fourth round pilot CRC screening programme or participants of the national CRC screening programme with sessile or flat colorectal polyps and
Patients aged 50-75 years, referred for diagnostic without coagulopathy. These will be patients with rectal blood loss, abdominal complaints, changed stool frequency, surveillance colonoscopy or iron deficiency anemia.

Exclusion criteria

Participants who did not sign informed consent
Pedunculated polyps
Patients with coagulopathie
Polyps that require piecemeal resection in more than 2 tempi
Participants with only polyps >21 mm
Participants with (suspected) colorectal cancer
Participants with suspicion of polyposis syndrome
Participants with inflammatory bowel disease

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	444
Type:	Anticipated

Ethics review

Approved WMO

Date:	22-04-2014
Application type:	First submission
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

ID: 21030
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL46939.018.14
OMON	NL-OMON21030

Study results

Summary results
Trial never started