Standard versus high definition colonoscopy.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20419

Source
NTR

Health condition

adenoma
screening colorectal cancer
colonoscopy

Sponsors and support

Primary sponsor: Maastricht University Medical Center
Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

Adenoma detection rate (ADR): The total number of adenomatous lesions (histological proven) divided by the number of patients per arm in all four groups.

Secondary outcome

1. The total number of polyps (adenomatous polyps, hyperplastic polyps, serrated adenomas

and inflammatory polyps);

2. The total number and percentage of non-polypoid or flat adenomas (Paris classification 0-IIa-c);

3. Proportion of patients with adenoma;

4. Proportion of patients with more than one polyp;

5. The total number and percentage of small polypoid (< 5mm) or flat lesions (height < ½ diameter);

6. The total number of advanced adenoma defined as adenoma with high grade dysplasia, villous components, intramucosal carcinoma and angio-invasive growth;

7. Number of missed lesions. This will be assessed after a follow up period of 60 months. Patients will be asked by a questionnaire whether they have had any colonoscopy within 60 months of the study period and if so, if any (pre)malignant lesions are found.

Study description

Background summary

Adenomatous polyps are precursors for colorectal cancer. Colonoscopy is considered to be the golden standard for the detection of colonic neoplasia. In theory, colon cancer can be prevented by removing all adenomatous polyps. However, there is a significant number of missed lesions, as assessed by back-to-back colonoscopy. This mis-rate can be attributed to lack of technique (short withdrawal time, insufficient bowel preparation) or due to technological causes like the quality of endoscopes to visualise small lesions and the possibility to look behind folds. Several technological innovations in both colonoscope design, performances and image processing are tested to improve colon visualisation and to lower the number of missed lesions. Data of studies regarding the effect on adenoma detection rate (ADR) by use of high definition (HD) endoscopes compared to standard colonoscopes are conflicting. This may result from differences in expertise of endoscopists, types of endoscopes and software applications. The ADR is the most frequently used primary outcome parameter with respect of screening of colorectal neoplasia and as indicator of quality assessment.
Recently, Pentax developed a digital mucosal enhancement function, called I-scan. This function is incorporated into Pentax HD colonoscopes. These endoscopes have the highest resolution available in flexible endoscopy nowadays. Several function modes are available for the enhancement of vessel structures and pit pattern. The mode that enhances the mucosal vessel architecture, thereby improving of detection of small mucosal lesions is called Surface Enhancement. Digital image processing with emphasis on certain wavelengths of white light like the Colon Mode will probably add additional mucosal and vascular details. The present

study is designed to assess the effect of HD colonoscopy alone or when combined with different I-scan functions compared to standard colonoscopy with respect to adenoma detection rate.

Study objective

Assess of the effect of HD colonoscopy alone or when combined with different I-scan functions compared to standard colonoscopy with respect to adenoma detection rate.

Study design

1. Single colonoscopy;

2. Questionaire after 60 weeks.

Intervention

1. Group A: Standard colonoscopes;

2. Group B: HD colonoscopes;

3. Group C: HD colonoscopes and I-scan Surface Enhancement (SE) (level 4);

4. Group D: HD colonoscopes and I-scan Surface Enhancement (SE) (level 4) and I-scan Colon Mode.

Contacts

Public
PObox 5800
R.J.J. Ridder, de
Maastricht 6202 AZ
The Netherlands
+31 (0)43 3875021
Scientific
PObox 5800
R.J.J. Ridder, de
Maastricht 6202 AZ
The Netherlands
+31 (0)43 3875021

Eligibility criteria

Inclusion criteria

A. One of the following reasons for colonoscopy:

1. Abdominal complaints;

2. Chronic diarrhea;

3. Iron deficiency anemia/ positive fecal occult blood test;

4. (Family) history of adenomatous polyps of colorectal cancer;

5. Screening colonoscopy to prevent CRC.
B. Sex: both males and females;

C. Age: above 40 years.

Exclusion criteria

1. Previous extended colon surgery;

2. Inflammatory bowel disease (IBD);

3. Hereditary polyposis syndromes;

4. Known gastrointestinal neoplasia before endoscopy (based on recent endoscopy or other imaging like CT).

Study design

Design

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

Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2010
Enrollment:	1472
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-03-2010
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	NL2141
NTR-old	NTR2265
Other	METC MUMC : MEC 09-2-96
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A