Standard colonoscopy versus high-definition colonoscopy with/without I-scan functions in the detection of colorectal neoplasia: a randomized multicenter study

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Assessment of the adenoma detection rate at colonoscopy using :A: Standard colonoscope B: High Definition colonoscope C: High Definition colonoscope with surface enhancementD: High Definition colonoscope with surface enhancement and Colon Mode

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Benign neoplasms gastrointestinal
Study type	Interventional

Summary

ID

NL-OMON33382

Source
ToetsingOnline

Brief title
Standard vs. high definition colonoscopy

Condition

- Benign neoplasms gastrointestinal
- Gastrointestinal neoplasms benign
- Gastrointestinal therapeutic procedures

Synonym
darmpoliep; voorstadium van dikke darmkanker

Research involving

Human

Sponsors and support

Primary sponsor: maag-darm-leverziekten
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: adenoma detection rate, colonoscopy, high definition, I-scan

Outcome measures

Primary outcome

The main study parameter will be the adenoma detection rate in all four groups.

Other end-points are: total number of polyps per patient, total number of flat lesions and time of procedure (withdrawal time). Patients are stratified to the treatment center.

Secondary outcome

Amount of small and flat lesions

Missed lesions (assessed by questionaire after 60 months)

Study description

Background summary

Adenomateous polyps are precursors for colorectal cancer. Colonoscopy is considered to be the golden standard for the detection of colonic neoplasia. However, there is a significant number of missed lesions, as assessed by back-to-back colonoscopy [1-2]. 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. Studies regarding the effect on adenoma detection rate (ADR) by use of high definition (HD) endoscopes compared to standard colonoscopes are conflicting. This might

be the result of different expertise of physicians, 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 compatible with their 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 some additional mucosal and vascular details. The present study is designed to assess the effect of HD colonoscopy alone or combined with different I-scan functions compared to standard colonoscopy with respect to adenoma detection rate.

Study objective

Assessment of the adenoma detection rate at colonoscopy using :
A: Standard colonoscope
B: High Definition colonoscope
C: High Definition colonoscope with surface enhancement
D: High Definition colonoscope with surface enhancement and Colon Mode

Study design

prospective randomized multicenter study

Intervention

colonoscopy

Study burden and risks

Risks are associated with colonoscopy in itself, but not with the type of endoscope or use of different I-scan functions. Differences in risks between study groups is unlikely. Serious risks are rare in colonoscopy and are especially related to interventions during endoscopy (ie polypectomy). Risks of diagnostic colonoscopy are significant bleeding in 0.005% and perforation in 0.01% of subjects. There is no increased risk for subjects participating in the study

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

patients (> 40 years old) undergoing diagnostic colonoscopy because of one of the following five indications: 1: abdominal complaints, 2: chronic diarrhea, 3: (family) history of adenomateous polyps or CRC, 4: rectal bloodloss and 5: iron deficiency anemia.

Exclusion criteria

Previous extended colon surgery, inflammatory bowel disease (IBD), Hereditary polyposis syndromes, known gastrointestinal neoplasia before endoscopy (based on recent endoscopy or other imaging like CT)
Patients <40 years

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2010
Enrollment:	984
Type:	Actual

Ethics review

Approved WMO

Date:	21-01-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL28389.068.09