Prospective randomized trial to compare the clinical efficiency (Adenoma Detection Rate) of G-EYE(TM) HD Colonoscopy with Standard HD Colonoscopy

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The aim of this study is to compare the additional diagnostic yield (adenoma detection rate) of G-EYE colonoscopy with that of standard high definition colonoscopy.

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

Summary

ID

NL-OMON41850

Source
ToetsingOnline

Brief title
Efficiency of G-EYE Colonoscopy

Condition

- Benign neoplasms gastrointestinal
- Gastrointestinal neoplasms benign

Synonym
Adenoma coli, colonic polyps

Research involving
Human

Sponsors and support

Primary sponsor: SMART Medical Systems Ltd
Source(s) of monetary or material Support: via Smart Medical Systems Ltd

Intervention

Keyword: Adenoma Detection Rate, Balloon scopy, Colonoscopy, G-EYE

Outcome measures

Primary outcome

G-EYE* colonoscopy detection rate of adenomas and serrated lesions compared to

the standard colonoscopy detection rate of the same.

Secondary outcome

Polyp and adenoma detection, procedure times and safety.

Study description

Background summary

Colorectal adenomas are the precursor lesions of colorectal cancers. Detection and resection of adenomas during colonoscopy can prevent the development of colorectal malignancies.
Approximately 30% of polyps are missed during Standard Colonoscopy (SC), e.g., due to polyps hidden behind colon folds and flexures. This work explores a novel device and technique for increasing polyp and adenoma detection during colonoscopy. It employs a unique balloon-colonoscope (G-EYE* Endoscope, Smart Medical Systems Ltd., Ra*anana, Israel), comprising a standard colonoscope having a reprocessable, permanently integrated balloon at its distal tip. The G-EYE balloon-colonoscope does not require pre-procedure preparation, mounting or use of any single-use accessory. Balloon pressure is controlled through a unique inflation system providing pre-determined, user-selectable, anchoring and intermediate (low) pressure levels. Furthermore, the balloon can be readily inflated to anchoring pressure upon interventional need, thus stabilizing the colonoscope in position, for faster and more controlled endoscopic interventions.

Study objective

The aim of this study is to compare the additional diagnostic yield (adenoma detection rate) of G-EYE colonoscopy with that of standard high definition colonoscopy.

Study design

This is a multicenter, two-arm, randomized, open-label study. Patients referred to colonoscopy for screening or surveillance workup, are randomized into two groups. Group A undergoes standard colonoscopy; group B undergoes G-EYE colonoscopy. During the G-EYE colonoscopy, the endoscope is inserted with the balloon deflated until the cecum is reached. Then, the balloon is inflated to intermediate pressure and the G-EYE colonoscope is withdrawn, thus straightening intestinal folds, smoothening colon topography and improving colon visibility. All detected polyps will be removed.

Participating hospitals include centers in Denmark, Germany, Israel, Poland, Spain, Turkey, and the United Kingdom.

Intervention

The NaviAid* G-EYE System is intended for the optical visualization, diagnosis and endoscopic treatment in the gastrointestinal tract. It is also intended for positioning of the endoscope in the gastrointestinal tract. The system consists of a normal Pentax coloscope, with an inflatable balloon attached around the tip. This balloon will be inflated during withdrawel.

Study burden and risks

All included patients have a medical indication for performing a colonoscopy. The general risk for complications, such as perforation, bleeding, and infection/sepsis, apply to both conventional and G-EYE colonoscopy. This G-EYE endoscoop is approved by the international standarization guidelines and had a EU certificate. The risk of complications is comparable with the risk of conventional endoscopes.

Assuming that the intervention (the G-EYE colonoscoop) has a better adenoma detection rate, less adenomas will be missed in the intervention group, theoratically leading to a smaller chance of developing a colorectal malignancy in the future at the individual level.

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

- Patiënts over 50 years old
- Referred to colonoscopy for screening, following positive FOBT testing, change of bowel habits or for surveillance colonoscopy (history of adenoma resection)
- The patient must understand and provide written consent for the procedure

Exclusion criteria

- Patients with inflammatory bowel disease, known polyposis syndrome, diverticulitis or toxic megacolon
- Patients with suspected chronic stricture potentially precluding complete colonoscopy
- Patients with a history of radiation therapy to abdomen or pelvis
- Pregnant or lactating female subjects
- Patients who are currently enrolled in another clinical investigation
- Patients with current oral or parenteral use of anticoagulants
- Patients with recent (within the last 3 months) coronary ischemia or CVA
- Previous colonic surgery (except for appendectomy)

Study design

Design

Study type:	Interventional
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):	16-11-2015
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	G-EYE colonoscope: Use of an inflatable balon during colonoscopy;attached to the colonoscope
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-04-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	31-12-2015
Application type:	Amendment
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
ClinicalTrials.gov	NCT01917513
CCMO	NL50819.068.14