POLYP DETECTION WITH THE PEERSCOPE SYSTEM*: A RANDOMIZED TANDEM COLONOSCOPY STUDY

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To compare the additional diagnostic yield obtained by using the PeerScope System* extended view vs. the diagnostic yield obtained by the Standard view colonoscopy.In addition, time measurements including time to cecum, time for withdrawal and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON37818

Source
ToetsingOnline

Brief title
PeerScope Clinical Trial

Condition

- Gastrointestinal conditions NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
colon cancer screening, large bowel observation

Research involving
Human

Sponsors and support

Primary sponsor: PeerMedical Ltd.
Source(s) of monetary or material Support: PeerMedical Ltd.

Intervention

Keyword: Colonoscopy, PeerScope, Polyp Detection Rate

Outcome measures

Primary outcome

• Standard view colonoscopy additional adenoma detection rate compared to the extended view additional adenoma detection rate using the PeerScope System*.

• Standard view colonoscopy additional polyp detection rate compared to the extended view additional polyp detection rate using the PeerScope System*.

Secondary outcome

• Performance of therapeutic interventions, such as biopsies, polypectomies, APC etc.

• Procedure time. The following will be recorded: a. Time for intubation to the cecum. b. Time for withdrawal from the cecum to the anal verge. c. Total procedure time.

A stopwatch is needed for 4. with stopping the timing of the procedure for any polypectomy performed and then restarting once the polypectomy is completed, meaning that purely procedure time is measured

• Sedation dosage.

• Patient satisfaction. Patient's pain at the end of the procedure will be recorded using VAS scale. Results of 24 hour telephone follow-up to assess for post-procedural patient satisfactory will be recorded on the CRF.

Study description

Background summary

Worldwide, colorectal cancer (CRC) is the third most common cancer in men and second most common cancer in women, accounting for an estimated total of 1.2 million new cases and 608,000 deaths per year. Colorectal cancer almost always starts in a benign growth called a polyp. Polyps originate in the inner lining of the colon, where they may be visible in a screening test known as colonoscopy. Recent research has shown that appropriate screening and treatment can alleviate much of the suffering associated with colorectal cancer and reduce the number of deaths caused by this malignancy.

Colonoscopy is a procedure for viewing the interior lining of the colon using a flexible endoscope called a colonoscope. Colonoscopy is a key tool for colorectal cancer screening and diagnosis of different diseases effecting the colon and ileum. The procedure allows therapeutic interventions such as polypectomy and biopsy collection. Recent data suggest that colonoscopy is superior to other screening procedures for the detection of colorectal cancer in people aged over 50. The American College of Gastroenterology has recently recommended that individuals over 50 at average risk of colon cancer should have elective colonoscopy every 10 years, and those at higher risk more frequently.
Several methods have been used for screening for colorectal cancer, including fecal occult blood testing, barium enema, flexible sigmoidoscopy, colonoscopy, and more recently, CT colonography (also known as virtual colonoscopy). Colonoscopy is currently regarded as the *gold standard* for detection of polyps and cancers in the colon.However, a growing number of studies have documented that significant numbers of lesions are missed during routine colonoscopy.

The primary reason for missing polyps and cancers is thought to be poor visualization of areas of the colon on the proximal aspects of haustral folds and rectal valves and behind flexures and the ileocecal valve. These locations tend to be hidden from the forward-viewing colonoscope and can generally be seen only through extensive manipulation of the colonoscope in an effort to flatten or *iron out* folds. Because they require substantial additional time, such maneuvers are not always performed during routine colonoscopy. Pickhardt, et al. mapped the locations of nonrectal neoplasms that were missed by colonoscopy but detected by CT colonography, and found that 67% were located on the proximal aspect of folds. A recently published, 10,292 person Canadian study found colonoscopy to have missed about every cancer in the right side of the colon, where cancers are harder to detect but about 40% arise. The study also found colonoscopy to have missed roughly a third of cancers in the left side of the colon. An additional study involving California Medi-Cal patients found similar results. There is mounting clinical evidence supporting the need to reduce the *miss rate* of standard colonoscopy.

Study objective

To compare the additional diagnostic yield obtained by using the PeerScope System* extended view vs. the diagnostic yield obtained by the Standard view colonoscopy.
In addition, time measurements including time to cecum, time for withdrawal and overall procedure time will be analyzed and reported for each group.

Study design

Patients who are scheduled for screening, surveillance or diagnostic colonoscopy will be recruited to the study and randomized to one of two groups. Each enrolled subject will undergo two *back-to-back* procedures.
Subjects in Group A (study group) will undergo a Standard view colonoscopy followed immediately by a PeerScope System* extended view colonoscopy. Subjects in Group B (control group) will undergo a PeerScope System* extended view colonoscopy followed immediately by a Standard view colonoscopy.
Results from the two groups will be analyzed and compared, with primary outcome measures being detection rates for total polyps and detection rates for adenomas. Secondary outcome measures will include withdrawal time, total procedure time and characteristics of polyps detected, including size and histological results.
Subjects will be followed through a 24 hour and a 7-days telephone interview for analysis of unexpected adverse events. Clinical results will be analyzed using various statistical measures of significance.

Up to 196 subjects (multi-center) will be recruited and randomized into one of two treatment arms.

Study burden and risks

The potential risks and benefits of participation in this study are clearly identified in the subject informed consent form and are to be explained to the patient prior to participation in the study.
Potential risks to the patient include the risks standard to colonoscopy procedures including perforation, bleeding, infection, discomfort and allergic reaction to sedation agents. All of these events could cause prolonged illness, permanent impairment of daily function or in rare cases death. Treatment includes, but is not limited to, abdominal surgery.
In a small percentage of cases, the colon may be perforated by a colonoscope, causing serious risk of infection to the patient. Gatto estimated the rate of perforation as 1.9/1000 procedures (or 0.19%) based on a large cohort of randomly sampled Medicare patients over the age of 65 who had screening colonoscopies, while other authors have described perforation rates above 1%.
As with any colonoscopy procedure, when using the PeerScope System* there is some risk of bowel perforation, pain, infection, bleeding due to therapeutic

procedures such as polypectomies and inflammation. The likelihood of occurrence of these risks is expected to be comparable to or better than conventional colonoscopy.
The potential benefits of the PeerScope System* are identical to those of standard colonoscopes. These benefits are: the ability to screen the entire colon for any abnormalities that may lead to colorectal cancer; the ability to perform therapeutic procedures such as polypectomies, when necessary. It can be assumed that the PeerScope System leads based on the wider field of view to higher detection rate of adenomas and thus reducing the risk for the development of colon cancer. However, as the device is investigational, this study is intended to validate this.

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

• Subject between the ages of 18 and 70;
• The patient is undergoing colonoscopy for colorectal cancer screening, for surveillance in follow-up of previous polypectomy or for diagnostic workup;
• Written informed consent must be available before enrollment in the trial.

Exclusion criteria

• Patients with a history of colonic resection.
• Patients with known (or newly diagnosed) inflammatory bowel disease.
• Patients with a personal history of polyposis syndrome.
• Patients with suspected colonic stricture potentially precluding complete colonoscopy.
• Patients with diverticulitis or toxic megacolon.
• Patients with a history of radiation therapy to abdomen or pelvis.
• Patients with acute lower GI-bleeding.
• Patients who are currently enrolled in another clinical investigation in which the intervention might compromise the safety of the patient*s participation in this study.
• Pregnant women and women with childbearing potential without adequate contraception.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-04-2012
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Peerscope
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-03-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL39353.041.12