Third Eye Retroscope Randomized Clinical Evaluation

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1. Study the overall miss rate of polyps detected with the third eye retroscope compared to standard colonoscopy.2. Study the overall miss rate of adenoma detected with the third eye retroscope compared to standard colonoscopy.3. Analyze the time...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON33766

Source
ToetsingOnline

Brief title
The *TERRACE* Study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
adenomata, polyps

Research involving
Human

Sponsors and support

Primary sponsor: Avantis medical systems. Inc
Source(s) of monetary or material Support: Avantis medical systems

Intervention

Keyword: Colonoscopy, Polypdetection, Third eye

Outcome measures

Primary outcome

1. Study the overall miss rate of polyps detected with the third eye retroscope compared to standard colonoscopy.

2. Study the overall miss rate of adenoma detected with the third eye retroscope compared to standard colonoscopy.

Secondary outcome

1. Study polyp characteristics, including the histological and pathological, of each for both groups.

2. Analyze the time observations, including time to cecum, time for withdrawal, the withdrawal time for both groups and total procedural times for each colonoscopy procedure.

Study description

Background summary

Colorectal cancer is the second most common cause of cancer death in the U.S. In 2007, an estimated 158,000 new cases of colorectal cancer were diagnosed in the U.S. and over 50,000 people died of the disease. Colorectal cancer generally causes no symptoms until it is far advanced. However, it can usually be successfully treated if it is detected early enough.
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.

Avantis Medical Systems has designed a retrograde auxiliary imaging device that is designed to allow visualization of *hidden areas* during colonoscopy by providing an additional, retrograde view that complements the antegrade view of the colonoscope. The retrograde view assists the endoscopist in visualizing the proximal aspect of haustral folds and rectal valves, as well as the areas behind flexures and the ileocecal valve. With this additional point-of-view, the endoscopist may be able to detect lesions that can be missed by the forward-viewing colonoscope.
In bench testing with anatomical models containing simulated polyps, use of the Third Eye Retroscope auxiliary imaging device was found to result in a markedly improved detection rate for simulated polyps located on the proximal aspect of haustral folds.

The purpose of this proposed study is to evaluate the polyp miss rate of standard colonoscopy and compare/analyze the diagnostic yield obtained from two differing colonoscopy techniques. In addition, time measurements including; time to cecum, time for withdrawal and overall procedure time will be analyzed and reported for each group.

Study objective

1. Study the overall miss rate of polyps detected with the third eye retroscope compared to standard colonoscopy.
2. Study the overall miss rate of adenoma detected with the third eye retroscope compared to standard colonoscopy.
3. Analyze the time observations, including time to cecum, time for withdrawal, the overall withdrawal time for both groups and the total procedural times for each colonoscopy procedure

Study design

All patients will undergo routine bowel preparation according a standardized protocol (4L oral laxative).
The endoscopist, the Principal Investigator, a clinical coordinator or a qualified designee of the Principal Investigator will qualify the subject candidate using the inclusion/exclusion criteria and will obtain informed consent of the patient, if he or she is proven suitable.
The subject will be randomized to Group A (study group: a complete routine colonoscopy followed immediately by a Third Eye colonoscopy) or Group B (control group; a Third Eye colonoscopy followed immediately by a complete routine colonoscopy). The subject will be notified of the treatment designation. The subject then will undergo back to back colonoscopy in accordance with the randomization process.

Intervention

The Avantis Third Eye Retroscope auxiliary imaging system includes a catheter, a cap and a video processor system.
The cap is placed on the tip of colonoscope prior to initiation of the procedure. The cap contains a polarizing filter that covers the light sources of the colonoscope, but it does not obstruct the colonoscope*s sensor and instrument channel.
The catheter is inserted through the instrument channel of the colonoscope after the tip of the colonoscope has been advanced to the cecum. The flexible catheter has a J-shaped distal tip with a capsule that contains a camera module with an image sensor, lens system and related circuitry. The catheter also has a light source consisting of a light emitting diode (LED). The diameter and the length of the catheter are designed to fit through a colonoscope*s instrument channel (minimum diameter of 3.7 mm). Its proximal end has a connector that snaps into an extension cable leading to the video processor.
The video processor system provides power for the catheter*s sensor and light source, controls the catheter*s lighting, controls and processes the signal from the catheter*s sensor and outputs the resulting signal to a monitor for display. Hardware and software supplied with the system allow single-frame still images to be recorded for documentation purposes. The Third Eye Retroscope device is sterilized by the EO process and is intended for single patient use only.

The order in which the two separate investigations will take place depends on the group to which the subject is randomized:
Group A: Subject will undergo a complete standard colonoscopy as the first procedure. Immediately after the first standard colonoscopy procedure a complete Third Eye colonoscopy will be completed.
Group B: Subject will undergo a complete Third Eye colonoscopy as the first procedure. Immediately after the first Third Eye colonoscopy procedure a complete standard colonoscopy will be completed.

Study burden and risks

The Third Eye Retroscope is similar in size to conventional tools used in the instrument channel of colonoscopes, including retrieval baskets, ultrasound probes, cytology brushes, biopsy forceps and polypectomy snares, and the risk from use of the Third Eye device should be less than or equal to the risk associated with these commonly-used devices.
Conventional colonoscopes do not allow retrograde viewing of the colon*s folds and flexures unless the colonoscope is retroflexed, a maneuver that is generally performed only in the rectum. This limited visualization likely contributes to documented miss rates for polyps and cancers in the colon.
The Third Eye Retroscope fits through the instrument channel of the colonoscope, and during withdrawal of the colonoscope it provides a retrograde view that can reveal abnormalities located in areas that can be hidden from the forward-viewing colonoscope, such as the proximal aspect of haustral folds and rectal valves and behind flexures and the ileocecal valve.

There is evidence from previous clinical studies to suggest that the retrograde view provided by the device actually enabled endoscopists to detect additional polyps - including many adenomatous polyps - that otherwise would not have been detected because they were hidden from the view of the conventional colonoscope.

It can be concluded that the risk/benefit ratio of the Avantis Third Eye Retroscope is acceptable when used according to the Instructions for Use.

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

1. The patient is undergoing colonoscopy for screening, for surveillance in follow-up of previous polypectomy or for diagnostic workup.

2. Age >= 18 years.
3. The patient must understand and provide written consent for the procedure.

Exclusion criteria

1. Age under 18.
2. Patients with a history of colonic resection.
3. Patients with inflammatory bowel disease.
4. Patients with a personal history of polyposis syndrome.
5. Patients with suspected chronic stricture potentially precluding complete colonoscopy.
6. Patients with diverticulitis or toxic megacolon.
7. Patients with a history of radiation therapy to abdomen or pelvis.
8. 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.
9. No written informed consent.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-03-2009
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Third eye endoscope; colonoscopy
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-02-2009
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	NL25230.041.08