Third Eye Panoramic Device Feasibility Evaluation

This study is enrolling participants by invitation only.

Sponsor:
Avantis Medical Systems

Information provided by (Responsible Party):
Avantis Medical Systems

ClinicalTrials.gov Identifier:
NCT02368977

First received: February 11, 2015
Last updated: February 20, 2015
Last verified: February 2015
History of Changes

Purpose

This study will evaluate the feasibility of using the Third Eye Panoramic device in conjunction with standard colonoscopes in a clinical setting.

Patients will undergo a colonoscopy procedure during which the study device will provide video imaging of areas of the colon that are difficult to evaluate with the colonoscope alone.

The utility of the device will be assessed from the impressions of the investigators and from telephone follow-up with subjects to assess for post-procedural complications.

Condition	Intervention
Colorectal Neoplasms	Device: Third Eye Panoramic device

Study Type: Interventional
Study Design: Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Diagnostic

Official Title: Third Eye Panoramic Device Feasibility Evaluation

Resource links provided by NLM:

MedlinePlus related topics: Colonoscopy

U.S. FDA Resources

Further study details as provided by Avantis Medical Systems:

Primary Outcome Measures:

- Device usability factors [Time Frame: 1 hour (average duration of procedure)] [Designated as safety issue: No]

  Device usability as measured by investigators' qualitative impressions regarding ease of use and any potential interference with function of colonoscope.

Secondary Outcome Measures:

- Device video factors [Time Frame: 1 hour (average duration of procedure)] [Designated as safety issue: No]

  Video image quality and ability to view areas behind folds as measured by investigators' qualitative impressions

- Patient safety assessed by number of subjects with adverse events as a measure of safety and tolerability [Time Frame: At time of procedure and up to 48 hours after completion of procedure] [Designated as safety issue: Yes]

Estimated Enrollment:	40
Study Start Date:	November 2013
Estimated Study Completion Date:	September 2015
Estimated Primary Completion Date:	September 2015 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: All subjects All subjects will undergo examination with a Third Eye Panoramic device in conjunction with a standard colonoscope to evaluate the feasibility of using the study device to provide video imaging of areas of the colon that are difficult to evaluate with the colonoscope alone.	Device: Third Eye Panoramic device A Third Eye Panoramic device will be attached to the tip of the colonoscope and will provide two additional views from laterally-oriented video cameras during the colonoscopy procedure.

Detailed Description:

The purpose of this study is to evaluate the feasibility of using the Third Eye Panoramic device along with a standard colonoscope as a means of enhancing the ability of endoscopists to view areas that are hidden from the view of the colonoscope.

Colonoscopy is generally agreed to be the best method for detecting and removing cancers and pre-cancerous adenomas in the colon. However, numerous studies have demonstrated that from 22% to over 40% of adenomas are missed during standard colonoscopy. More importantly, 12% of large adenomas (at least 1 cm) are missed even by expert endoscopists using meticulous technique with the best available equipment, and these large adenomas are the ones that are most likely to transform into cancer.

Factors such as quality of bowel cleansing and time spent examining the colonic mucosa have been shown to affect miss rates. However, comparison with the results of CT colonography has shown that 2/3 of missed adenomas are located behind folds in the wall of the colon, in areas that are very difficult to see with a standard forward-viewing colonoscope.

When clipped onto the tip of a standard colonoscope, the Third Eye Panoramic device provides two additional miniature video cameras and light sources that offer views to the left side and right side of the colonoscope's tip. These lateral views complement the forward view of the colonoscope's camera to result in a "panoramic" view of over 300°. This extreme wide-angle view allows the endoscopist to examine the areas located behind folds.

In this study, each subject will undergo a colonoscopy procedure utilizing the Third Eye Panoramic device along with a standard colonoscope.

The investigators will evaluate issues related to usability and safety based on their experience and impressions, with telephone follow-up with subjects to assess for any post-procedural complications.

Eligibility

Ages Eligible for Study:	up to 75 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion Criteria:

1. The patient is undergoing colonoscopy for screening, for surveillance in follow-up of previous polypectomy or for diagnostic workup.
2. The patient must understand and provide written consent for the procedure.

Exclusion Criteria:

1. Patients >75 years of age;
2. Patients with a history of colonic resection;
3. Patients with suspected chronic stricture potentially precluding complete colonoscopy;
4. Patients with diverticulitis or toxic megacolon;
5. Patients with a history of radiation therapy to abdomen or pelvis;
6. 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.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02368977

Locations

United States, New York

New York Hospital Queens
Flushing, New York, United States, 11355

Sponsors and Collaborators

Avantis Medical Systems

Investigators

Principal Investigator: Moshe Rubin, MD New York Hospital Queens - Weill Cornell **Medical** College

More Information

No publications provided

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Health Authority:	United States: Food and Drug Administration

Keywords provided by Avantis Medical Systems:
Colonoscopy
Polyps
Adenomas

Additional relevant MeSH terms:

Colorectal Neoplasms	Intestinal Diseases
Colonic Diseases	Intestinal Neoplasms
Digestive System Diseases	Neoplasms
Digestive System Neoplasms	Neoplasms by Site
Gastrointestinal Diseases	Rectal Diseases
Gastrointestinal Neoplasms	

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