Clinical trial registration statement

November 7, 2017

Name of Journal: *World Journal of Gastroenterology*

ESPS Manuscript NO: 35918

Manuscript Type: Randomized Controlled Trial

Title: A Multicenter, Randomized Study to Optimize Bowel Preparation for Colon Capsule Endoscopy

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This study and protocol was registered with www.clinicaltrials.gov Registry ID# NCT02481219. See the attached document for verification.

Sincerely,

David Kastenberg M.D.

Trial record **1 of 1** for: NCT02481219

Previous Study | Return to List | Next Study

Optimization of the Bowel Preparation Regimen for the PillCam® COLON 2 Capsule Endoscopy Procedure

This study has been completed.

Sponsor:
Medtronic - MITG

ClinicalTrials.gov Identifier:
NCT02481219

First Posted: June 25, 2015
Last Update Posted: March 7, 2017

Information provided by (Responsible Party):
Medtronic - MITG

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Purpose

This study is designed to determine the optimal bowel preparation regimen for PillCam® COLON 2 Capsule Endoscopy System (CCE) procedures in average risk patients.

Patients will be randomized to receive one of two bowel preparation regimens prior to PillCam CCE.

Condition	Intervention
Colorectal Cancer Screening	Device: PillCam® COLON 2 procedure-CONTROL

	Drug: Senna tablets Drug: PEG Drug: Metoclopramide Drug: Erythromycin Drug: SUPREP oral sulfate solution Drug: Bisacodyl Drug: SUPREP oral sulfate solution with Gastrografin

Study Type: Interventional

Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: None (Open Label)
Primary Purpose: Diagnostic

Official Title: COVGIC20482: A Multicenter, Consecutive, Randomized Study to Optimize the Bowel Preparation Regimen for the PillCam COLON 2 Capsule Endoscopy Procedure

Resource links provided by NLM:

MedlinePlus related topics: Endoscopy

U.S. FDA Resources

Further study details as provided by Medtronic - MITG:

Primary Outcome Measures:

- Bowel Cleansing Level of Two Different Bowel Preparation Methods for PillCam® Colon Capsule Endoscopy (CCE) [Time Frame: Within two weeks of study procedure]

  The primary endpoint is the bowel cleansing level, as determined by a standardized 4-point grading scale, assessed in total and by segment (cecum, ascending, transverse, descending/sigmoid, and rectum).

Secondary Outcome Measures:

- Comparing Polyp Detection Rate of Two Different Bowel Preparation Methods for PillCam CCE [Time Frame: an expected average of 3 weeks from study procedure]

  Will be assessed from RAPID video in total and by segment

- Colonic Transit Time of Two Different Bowel Preparation Methods for PillCam CCE [Time Frame: an expected average of 3 weeks from study procedure]

  Colonic transit time of two different bowel preparation was assessed from RAPID video in total and by segment

- Comparing of Completion Rate of Capsule of Two Different Bowel Preparation Methods for PillCam CCE [Time Frame: an expected average of 3 weeks from study procedure]

  Will be assessed from RAPID video in total and by segment

- Excretion Rate of Capsule Within 12 Hours of Two Different Bowel Preparation Methods for PillCam CCE [Time Frame: an expected average of 3 weeks from study procedure]

  Will be assesses by applicable case report form (CRF)

- Adverse Events Rate Between Two Different Bowel Preparation Methods for PillCam CCE [Time Frame: Adverse Events (AE) were collected starting from the screening visit and until 5-9 days following the PillCam procedure day.]

  Will be assesses by applicable CRF

Enrollment:	122
Study Start Date:	May 2015
Study Completion Date:	February 2016
Primary Completion Date:	January 2016 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: Bowel preparation regimen -Control Regimen includes administration of: Drug: 4 Senna tablets 2 days before the procedure, Drug: 2-liters of polyethylene glycol (PEG) on the evening before the procedure Drug: 2-liters of PEG on the morning of the procedure, Drug:10mg Metoclopramide or 250 mg Erythromycin Drug: 2 SUPREP oral sulfate solution Drug: 10mg Bisacodyl suppository.	Device: PillCam® COLON 2 procedure-CONTROL Drug: Senna tablets Drug: PEG Drug: Metoclopramide Drug: Erythromycin Drug: SUPREP oral sulfate solution Drug: Bisacodyl
Experimental: Bowel preparation regimen-Test Regimen includes administration of:	Device: PillCam® COLON 2 procedure-CONTROL Drug: Senna tablets Drug: PEG Drug: Metoclopramide Drug: Erythromycin

Drug: 4 Senna tablets 2 days before the procedure, Drug: 2-liters of PEG on the evening before the procedure Drug: 2-liters of PEG on the morning of the procedure, Drug:10mg Metoclopramide or 250 mg Erythromycin Drug: 2 SUPREP oral sulfate solution with Gastrografin Drug: 10mg Bisacodyl suppository.	Drug: Bisacodyl Drug: SUPREP oral sulfate solution with Gastrografin

Detailed Description:

This is a multicenter, prospective, consecutive, randomized study. Average-risk subjects undergoing CCE without optical colonoscopy will be consecutively enrolled and randomized 1:1 to receive one of two bowel preparation regimens prior to PillCam CCE.

Subjects will be enrolled at 5-10 clinical sites in the United States. Subjects who meet the eligibility criteria will be screened for study participation at a baseline visit and will be evaluated on the procedure day or until capsule excretion. A telephone follow-up will be conducted 5 to 9 days post-capsule ingestion to verify capsule excretion, assess patient well-being, and capture any adverse events.

Eligibility

Information from the National Library of Medicine NIH NLM

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, Learn About Clinical Studies.

Ages Eligible for Study:	50 Years to 75 Years (Adult, Senior)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion Criteria:

1. Subject is between 50 and 75 years of age.
2. Subject is classified as average risk per the American Gastroenterological Association Guidelines on Colorectal Cancer Screening: Individuals without a personal or family history of colorectal cancer (CRC) or adenomas, inflammatory bowel disease, or high-risk genetic syndromes.
3. Subject is willing and able to participate in the study procedures and to understand and sign the informed consent.

Exclusion Criteria:

1. Subject with history of polyps (including those identified by computed tomography [CT], optical colonoscopy, sigmoidoscopy, etc.).
2. Subject with history of negative colon assessment (including CT, optical colonoscopy, sigmoidoscopy etc.) within 5 years as these subjects would be defined not requiring screening in this time frame.
3. Subject with suspected or diagnosed with hematochezia, melena, iron deficiency with or without anemia, or any other rectal bleeding, including positive fecal occult blood test of any variety.
4. Subject with any condition believed to have an increased risk of capsule retention such as suspected or known bowel obstruction, stricture, or fistula.
5. Subject with dysphagia or any swallowing disorder.
6. Subject with serious medical conditions that would increase the risk associated with capsule or colonoscopy that are so severe that screening would have no benefit.
7. Subject with a cardiac pacemaker or other implanted electromedical device.
8. Subject expected to undergo MRI examination within 7 days after ingestion of the capsule.
9. Subject with clinical evidence of renal disease, including clinically significant laboratory abnormalities of renal function within the past 6 months, or at any time in the past if not tested within the last 6 months, defined as creatinine, blood urea nitrogen (BUN), and/or glomerular filtration rate (GFR) outside of the local laboratory reference range.
10. Subject with known gastrointestinal motility disorders.
11. Subject with allergies or known contraindication to the medications or preparation agents used in the procedure as described in the relevant instructions for use.
12. Subject with comorbidities which, in the opinion of the investigator, will not be appropriate for the study or the subject has an estimated life expectancy of less than 6 months.
13. Subject is considered to be part of a vulnerable population (e.g. prisoners or those without sufficient mental capacity).
14. Subject is pregnant, suspected pregnant, or is actively breast-feeding. Females of child-bearing potential will be required to provide either a urine pregnancy test or serum pregnancy test as part of the participant's standard of care regardless of their participation in the study (except for subjects who are surgically sterile or are post-menopausal for at least two years).
15. Subject has participated in an investigational drug or device research study within 30 days of enrollment that may interfere with the subject's safety or ability to participate in this study.

Contacts and Locations

Information from the National Library of Medicine NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02481219***

Locations

United States, Alabama

Pinnacle Research Group, LLC
Anniston, Alabama, United States, 36207

United States, Indiana

Indiana University Hospital
Indianapolis, Indiana, United States, 46202

Indianapolis Gastroenterology and Hepatology
Indianapolis, Indiana, United States, 46237

United States, Ohio

Dayton Gastroenterology
Dayton, Ohio, United States, 45440

United States, Pennsylvania

Thomas Jefferson University
Philadelphia, Pennsylvania, United States, 19107

United States, Tennessee

Franklin Gastroenterology, PLLC
Franklin, Tennessee, United States, 37067

Sponsors and Collaborators

Medtronic - MITG

Investigators

Principal Investigator: Douglas K Rex, Dr.

More Information

Responsible Party:	Medtronic - MITG
ClinicalTrials.gov Identifier:	NCT02481219 History of Changes
Other Study ID Numbers:	MA-205

First Submitted: May 19, 2015
First Posted: June 25, 2015
Results First Submitted: March 6, 2016
Results First Posted: July 11, 2016
Last Update Posted: March 7, 2017
Last Verified: June 2015

Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: No

Keywords provided by Medtronic - MITG:
Polyps
Capsule endoscopy
Bowel preparation regimen
Average risk patients for colorectal cancer screening

Additional relevant MeSH terms:

Colorectal Neoplasms
Intestinal Neoplasms
Gastrointestinal Neoplasms
Digestive System Neoplasms
Neoplasms by Site
Neoplasms
Digestive System Diseases
Gastrointestinal Diseases
Colonic Diseases
Intestinal Diseases
Rectal Diseases
Pharmaceutical Solutions
Metoclopramide
Erythromycin stearate
Erythromycin
Erythromycin Estolate
Erythromycin Ethylsuccinate
Bisacodyl
Antiemetics
Autonomic Agents
Peripheral Nervous System Agents
Physiological Effects of Drugs
Gastrointestinal Agents
Dopamine D2 Receptor Antagonists
Dopamine Antagonists
Dopamine Agents
Neurotransmitter Agents
Molecular Mechanisms of Pharmacological Action
Anti-Bacterial Agents
Anti-Infective Agents