Efficacy and Safety of Prepopik® in Children for Overall Colon Cleansing in Preparation for Colonoscopy (Prepopik PREA)

ClinicalTrials.gov Identifier: NCT01928862

Recruitment Status : Completed
First Posted : August 27, 2013
Results First Posted : April 23, 2018
Last Update Posted : April 23, 2018

Sponsor:
Ferring Pharmaceuticals

Information provided by (Responsible Party):
Ferring Pharmaceuticals

Study Description

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Brief Summary:
To study the efficacy and safety of Prepopik® in children aged 9 to 16 years for overall colon cleansing in preparation of colonoscopy

Condition or disease	Intervention/treatment	Phase
Need for Bowel Preparation	Drug: Prepopik® ½ Sachet x 2 (9-12 years) Drug: Prepopik® 1 Sachet x 2 (9-12 years) Drug: Oral polyethylene glycol (PEG) based preparation (9-12 years) Drug: Prepopik® 1 Sachet x 2 (13-16 years) Drug: Oral polyethylene glycol (PEG) based preparation (13-16 years)	Phase 1 Phase 2

Study Design

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Study Type :
Interventional (Clinical Trial)

Actual Enrollment :
78 participants

Allocation:
Randomized

Intervention Model:
Parallel Assignment

Masking:
Single (Outcomes Assessor)

Primary Purpose:
Treatment

Official Title:
A Randomized, Assessor-Blind, Multicenter, Dose-Ranging Study Comparing the Safety and Efficacy of Prepopik® Versus Polyethylene Glycol Preparation (Local Standard of Care) in Children Aged 9 Years to 16 Years

Actual Study Start Date :
June 3, 2014

Actual Primary Completion Date :
February 15, 2017

Actual Study Completion Date :
March 16, 2017

Resource links provided by the National Library of Medicine

Genetics Home Reference related topics: Progressive external ophthalmoplegia

Drug Information available for: Citric acid / magnesium oxide / sodium picosulfate

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: Prepopik® ½ Sachet x 2 (9-12 years) Prepopik® ½ Sachet x 2 (9-12 years)	Drug: Prepopik® ½ Sachet x 2 (9-12 years) Other Name: Prepopik®
Experimental: Prepopik® 1 Sachet x 2 (9-12 years) Prepopik® 1 Sachet x 2 (9-12 years)	Drug: Prepopik® 1 Sachet x 2 (9-12 years) Other Name: Prepopik®
Active Comparator: Oral polyethylene glycol (PEG) based preparation (9-12 years) Local standard of care	Drug: Oral polyethylene glycol (PEG) based preparation (9-12 years)
Experimental: Prepopik® 1 Sachet x 2 (13-16 years) Prepopik® 1 Sachet x 2 (13-16 years)	Drug: Prepopik® 1 Sachet x 2 (13-16 years) Other Name: Prepopik®
Active Comparator: Oral polyethylene glycol (PEG) based preparation (13-16 years) Local standard of care	Drug: Oral polyethylene glycol (PEG) based preparation (13-16 years)

Outcome Measures

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Primary Outcome Measures :

1. Percentage of Participants Defined by "Excellent" or "Good" in the Aronchick Scale [Time Frame: On the day of colonoscopy]

   Aronchick scale is a 4-point scale that grades colon cleansing as Excellent (>90% of mucosa seen, mostly liquid stool, minimal suctioning needed for adequate visualization), Good (>90% of mucosa seen, mostly liquid stool, significant suctioning needed for adequate visualization), Fair (>90% of

mucosa seen, mixture of liquid and semisolid stool, could be suctioned and/or washed) or Inadequate (<90% of mucosa seen, mixture of semisolid and solid stool which could not be suctioned or washed). The participant is considered to be a responder if overall colon cleansing is "excellent" or "good" on this 4-point scale.

Secondary Outcome Measures :

1. Number of Participants With Adverse Events [Time Frame: Up to 33 days after colonoscopy]

   An adverse event (AE) is defined as any untoward medical occurrence in a participant taking part in a clinical trial. Proportion of participants with AE are presented.

2. Number of Participants With Abnormal Findings in Laboratory Tests [Time Frame: From up to 42 days prior to colonoscopy, at the day of colonoscopy, and up to 7 days post colonoscopy]

   Proportion of participants with abnormal findings in laboratory tests are presented.

3. Number of Participants With Abnormal Findings in Physical Examination [Time Frame: From up to 42 days prior to colonoscopy, on the day of randomization, and at the day of colonoscopy]

   Complete physical examination was conducted at screening and directed physical examinations at other time-points. Directed physical examinations are presented.

4. Number of Participants Who Took the Assigned Dose for Colon Cleansing [Time Frame: Approx. 1 day (From the day before colonoscopy to the day of colonoscopy)]

   The proportion of participants who took the assigned dose of Prepopik® was assessed.

5. Number of Participants in Each Category of the "Subject's Tolerability and Satisfaction Questionaire" [Time Frame: 1 day of colonoscopy]

   Subject's Tolerability and Satisfaction Questionnaire consists of three questions. Question (Q)1 was "How easy was it to drink the bowel cleanout medicine?" and Q2 was "How did the bowel cleanout medicine taste?". Q3 had five subparts namely: 1. "How often did your tummy hurt since you started the medicine?" and 2. "How often did you feel fullness in your tummy, since you started the cleanout?" and 3. "How often did you wake up last night" and 4. "How often did you feel sick to your stomach (nausea) since you started the cleanout?' and 5. "How much were you bothered by going to the washroom since you started the cleanout?"

   Satisfactory was defined as a response of 1 (Very Easy) or 2 (Easy) on Q1 and a response of 1 (Very Well) or 2 (Well) on Q2.

   Tolerable was defined as a response of 1 (Never) or 2 (Rarely) to the five subparts specified in Q3.

Eligibility Criteria

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Information from the National Library of Medicine

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:

9 Years to 16 Years (Child)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

No

Criteria

Inclusion Criteria:

- Male or female, aged 9 years to 16 years, inclusive, being scheduled to undergo elective colonoscopy
- Subjects must have had 3 or more spontaneous bowel movements per week for 1 month prior to the colonoscopy
- Female subjects of childbearing potential must undergo a pregnancy test at screening and again at randomization

Exclusion Criteria:

- Acute surgical abdominal conditions (e.g., acute obstruction or perforation)
- Hospitalized for inflammatory bowel disease
- Any prior colorectal surgery, excluding appendectomy, hemorrhoid surgery, or prior endoscopic surgical procedures
- Colon disease (history of colonic cancer, toxic megacolon, toxic colitis, idiopathic pseudo obstruction, hypomotility syndrome, colon resection)
- Ascites

- Gastrointestinal disorder (active ulcer, outlet obstruction, retention, gastroparesis, ileus)
- Upper gastrointestinal surgery (gastric resection, gastric banding, gastric bypass)
- Significant cardiovascular disease as determined by the investigator
- If subject has a history of renal insufficiency, serum creatinine and potassium must be within normal limits
- Any clinically significant laboratory value at screening, including pre- existing electrolyte abnormality, based on clinical history
- Hypersensitivity to active ingredients

Contacts and Locations

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Information from the National Library of Medicine

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): ***NCT01928862***

Locations

United States, Alabama

University of Alabama
Birmingham, Alabama, United States

United States, California

University California San Diego - Rady's Children's Hospital
San Diego, California, United States

United States, Indiana

IU Medical Center / Riley Hospital
Indianapolis, Indiana, United States

United States, Maryland

John Hopkins
Baltimore, Maryland, United States

United States, New York

Stony Brook Children's
Stony Brook, New York, United States

United States, Ohio

Nationwide Children's Hospital
Columbus, Ohio, United States

United States, Pennsylvania

Children's Hospital of Philadelphia
Philadelphia, Pennsylvania, United States

Children's Hospital of Pittsburgh
Pittsburgh, Pennsylvania, United States

United States, Tennessee

Vanderbilt University Medical Center
Nashville, Tennessee, United States

Sponsors and Collaborators

Ferring Pharmaceuticals

Investigators

Study Director: Clinical Development Support Ferring Pharmaceuticals

Study Documents (Full-Text)

Documents provided by Ferring Pharmaceuticals:

Study Protocol [PDF] July 28, 2014

Statistical Analysis Plan [PDF] February 16, 2017

More Information

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Responsible Party:
Ferring Pharmaceuticals

ClinicalTrials.gov Identifier:
NCT01928862 History of Changes

Other Study ID Numbers:
000103

First Posted:
August 27, 2013 Key Record Dates

Results First Posted:

April 23, 2018

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