ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Study Comparing PEG 3350 Laxative to Placebo in the Treatment of Occasional Constipation (Study CL2007-12)(P08216)

This study has been completed.

Sponsor:
Bayer

Information provided by (Responsible Party):
Bayer

ClinicalTrials.gov Identifier:
NCT00770432

First received: October 9, 2008
Last updated: February 20, 2015
Last verified: February 2015
History of Changes

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

Purpose

Randomized, placebo-controlled, double blind study. 203 subjects entered the study to compare the effect on occasional constipation of polyethylene glycol 3350 to placebo. Subjects took one of study treatments up to 7 days.

Condition	Intervention	Phase
Constipation	Drug: Polyethylene glycol 3350 Other: Placebo, maltodextrin 500 powder for solution	Phase 4

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Randomized, Placebo-Controlled, Double-Blind, Trial of Polyethylene Glycol 3350 Laxative for the Treatment of Occasional Constipation.

Resource links provided by NLM:

MedlinePlus related topics: Constipation

Drug Information available for: Polyethylene Macrogol

U.S. FDA Resources

Further study details as provided by Bayer:

Primary Outcome Measures:

- Number of Participants With a Complete Resolution at the Final Visit [Time Frame: 24 hours to 3 days after last dose of seven day treatment period.] [Designated as safety issue: No]

  A resolution was recorded if the participant has no occurrence of two or more consecutive unsuccessful bowel movements for the rest of the study following the first successful bowel movement.

Secondary Outcome Measures:

- Diary Ratings in Visual Analog Scale Format (Bowel Movement Control, Gas, Bloating, Abdominal Discomfort/Cramping, Well-being) [Time Frame: 24 hours to 3 days after last dose of seven day treatment period.] [Designated as safety issue: No]

  This is not a prespecified key secondary outcome; therefore, results will not be disclosed.

- Binary Outcomes (Bowel Movement Satisfaction, Bowel Moevement Sense of Completion). [Time Frame: 24 hours to 3 days after last dose

of seven day treatment period.] [Designated as safety issue: No]

This is not a prespecified key secondary outcome; therefore, results will not be disclosed.

Enrollment: 203
Study Start Date: November 2007
Study Completion Date: January 2008
Primary Completion Date: January 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: Polyethylene glycol 3350 powder for solution MiraLAX® (polyethylene glycol 3350 powder for solution)	Drug: Polyethylene glycol 3350 Polyethylene glycol 3350 powder for solution. Single dose (17 grams in 4 to 8 ounces of beverage) for 7 days. Other Name: MiraLAX®
Placebo Comparator: Placebo MALTRIN 500® M500 (maltodextrin 500)	Other: Placebo, maltodextrin 500 powder for solution Maltodextrin 500 powder for solution, One single dose (one capful) in any 4 - 8 ounces beverage for 7 days. Other Name: MALTRIN® 500 powder for solution

Eligibility

Ages Eligible for Study: 17 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Subjects (or parents/guardians of minors) must demonstrate their willingness to participate (or to have their children/wards participate) in the study and comply with its procedures by signing a written informed consent. Minor subjects must provide written assent.
- Subjects must be 17 years of age or older.
- Subjects must present with a current diagnosis of untreated constipation for 7 days or less based on having signs/symptoms of straining and hard or lumpy stools OR the inability to have a BM within 48 hours prior to randomization into the trial.
- Subjects must be OTC laxative users for the treatment of occasional constipation (defined as using a nonprescription laxative to treat at least 3 episodes of constipation within the last 12 months prior to randomization).
- Subjects must be willing to use study drug for up to 7 days as directed, and must agree to record bowel movement (frequency, consistency, etc.) accurately and consistently in a daily diary, and make two clinic visits.
- Subjects must be otherwise in good health, as determined by physical exam and medical history.
- Subjects must agree not to use any other products to treat their constipation during the course of the study.
- Subjects must agree not to use any medication known to cause constipation during the course of the study.
- Subjects must agree to maintain a similar diet from the week prior to randomization through end of study.
- Female subjects must be either surgically sterile, 2 years post-menopausal, or they attest that they are using an acceptable method of contraception (including hormonal birth control, IUD, double barrier methods, or vasectomized partner). In females of childbearing potential, the urine pregnancy test (HCG) must be negative at Baseline.
- Subjects must be able to read the diaries in English.

Exclusion Criteria:

- Subjects currently under a doctor's care and treatment for constipation.
- Subjects having current constipation episode for more than one week prior to randomization.
- Subjects that have a history of chronic constipation due to any underlying cause (inflammatory bowel disease, etc.).
- Subjects have a history of more than 3 months of constipation in the past year.
- Subjects have severe abdominal pain as the predominant constipation symptom.
- Subjects who have previously used a polyethylene glycol laxative.
- Subjects who have celiac disease or known gluten sensitivity.
- Subjects who have a history of colorectal cancer, anal abscess, anal fistula, anal fissure, anal stenosis, gastric retention or obstruction, bowel resection, rectocele, or colostomy.
- Subjects with known renal or hepatic insufficiency.

- Subjects with gastrointestinal bleeding or acute infection.
- Subjects with a history of alcohol or drug abuse.
- Subjects with a history of psychiatric disorders.
- Subjects with a history of significant ongoing medical problems, including kidney disease, or who are scheduled for surgical procedures.
- Subjects currently taking or taken within 7 days of randomization a concomitant medication that causes constipation including for example opiates, antidepressants, SSRI's, antimotility agents, and anticholinergics, etc.
- Subjects who plan to use laxatives during the treatment period other than the study medication.
- Subjects who, in the opinion of the investigator, should not be included in the study for any reason, including inability to follow study procedures.
- Subjects who have participated in an investigational clinical surgical, drug or device study within the past 30 days.
- Subjects who are pregnant or lactating.
- Subjects who are allergic to polyethylene glycol or maltodextrin.
- Subjects who are employed or have immediate family members employed by a company that manufactures laxative products.

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.

No Contacts or Locations Provided

More Information

No publications provided

Responsible Party:	Bayer
ClinicalTrials.gov Identifier:	NCT00770432 History of Changes
Other Study ID Numbers:	18130, CL2007-12, P08216
Study First Received:	October 9, 2008
Results First Received:	June 24, 2009
Last Updated:	February 20, 2015
Health Authority:	United States: Institutional Review Board

Keywords provided by Bayer:
Human Experimentation

Additional relevant MeSH terms:

Constipation	Pharmaceutical Solutions
Signs and Symptoms	Gastrointestinal Agents
Signs and Symptoms, Digestive	Pharmacologic Actions
Laxatives	Therapeutic Uses

ClinicalTrials.gov processed this record on December 21, 2015