

Microbia Inc: Constipation-IBS (HUM13192)

PI: William Chey, MD, pager 5684

Study Coordinator: Lina, pager: 0321, Tel: 734.936.2761, lnahlawi@med.umich.edu

Study Title: A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Dose-Range-Finding, Parallel-Design, Phase 2 Trial of Oral Linaclotide Acetate Administered to Patients with Irritable Bowel Syndrome with Constipation

Study Purpose:

The purpose of this study is to test the safety and effectiveness of the investigational drug (called Linaclotide) in subjects with IBS-C.

Mechanism of Action:

Acts by increasing chloride and bicarbonate secretion in the intestinal lumen. GC-C agonists also inhibit colonic fluid absorption.

Study Design:

A 20-week duration study requiring 8 visits to the office, and involving a screening period, followed by randomization to one of the four treatment arms of Linaclotide, with an option to enroll in an open-label extension study. Clinic visits are scheduled at 4-weekly intervals. Study procedures include: physical exam, vital signs, blood tests and urinalysis, ECG, all free of charge.

Compensation:

\$50 for each completed study visit.

Eligibility:

- men and women ages 18-70
- diagnosed with constipation-IBS
- had a normal colonoscopy within the past 5 years

Pharmos Corp, Treating IBS-D in Adult Females (HUM13638)

PI: William Chey, MD, pager 5684

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Study Title:

A Double-Blind, Randomized, Placebo-Controlled Phase 2b Study of 100, 200, and 300 mg BID Dextofisopam in Female Outpatients with Irritable Bowel Syndrome

Mechanism of Action:

Dextofisopam acts centrally on subcortical benzodiazepine receptors, and may exert anti-inflammatory activity via cytokine inhibition. It reduces stimulated activity and decreases contractions evoked by colorectal distension.

Study Design:

A 2-week treatment-free screening period, a 12-week blinded treatment period, followed by a treatment-free withdrawal period, and requires 6 visits to the research office. Study procedures include: physical exam, vital signs, lab testing, and ECG, all free of charge to participants.

Compensation:

\$50 for each completed visit, a total of \$300 for completing the whole study.

Eligibility:

- 1. female age 18 - 65
- 2. diagnosed with IBS-D
- 3. must not have history of suicide attempt or ideation

Prometheus Laboratories: The Value of Diagnostic Testing in IBS

IRB Archive #: 2003-0411

Principal Investigator: Bill Chey, pager #5684

Study Coordinator: Dr. Borko Nojkov, pager #30646, 734-936-8750,

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Study Purpose:

To evaluate the usefulness of routine diagnostic testing in patients with suspected IBS. Tests to be evaluated include CBC, comprehensive, metabolic profile, TSH, ESR, stool tests where appropriate. Patients will also undergo serological testing for celiac disease and IBD.

Study Design:

Patients meeting eligibility criteria will be enrolled in an observational cohort study that is 1-day, 1-visit. Subjects will undergo standardized diagnostic evaluation to exclude organic gastrointestinal disease as recommended by the American Gastroenterological Association; this will include various serological examinations as well as lower gastrointestinal endoscopy. Controls will consist of patients undergoing colonoscopy for colorectal cancer screening or surveillance purposes. These patients will also undergo serologic testing for sprue and IBD in addition to their scheduled colonoscopy.

Eligibility for Subjects:

- Males and females 18-75 yrs of age
- Patients previously diagnosed with IBS with some component of diarrhea
- Colonoscopy within past 5 years required

Eligibility for Controls:

- Males and females 18-75 yrs of age
- Colonoscopy required

Assessment of the Whole Gut Transit Time Using the SmartPill Capsule: A Multicenter Study (HUM0004866)

Principal Investigator: Richard Saad, Pager #14066

Study Coordinator: Borko Nojkov, Pager #30646, 734-936-8750, bnojkov@med.umich.edu

Study purpose:

To compare two methods of measuring motility of the gastrointestinal tract for patients with constipation as compared to healthy controls.

Study description:

A novel technology, named the SmartPill GI Monitoring System, measures intraluminal gastrointestinal pH, pressure and temperature. Through such measurements, gastrointestinal transit can be determined. This study is being done to compare this non-invasive method to the conventional Sitzmark radiopaque markers test in healthy subjects and patients with constipation. Subjects will undergo a screening visit to verify eligibility. There are at least 3 visits. The testing visit will last up to 8 hours, and the 2 follow-up visits will last approximately 1 hour.

Eligibility:

Males and females 65-80 years old

Both healthy subjects and patients with chronic constipation

Constipated subjects must have at least 3 bowel movements per week females must be practicing effective birth control and must not be pregnant or lactating no abdominal surgery within last 3 months, no history of diverticulitis, diverticular stricture, and other intestinal strictures, no medications that affect gastrointestinal motility for 3 days prior to testing and throughout, no medications that may alter gastric pH taken during study, no tobacco, alcohol within 8 hours prior to testing and throughout monitoring period (up to 5 days), no use of medical devices such as pacemakers, infusion pumps, insulin pumps, symptoms must be for at least 1 year duration

Compensation: \$400 for completing the study

Microbia Inc: Treating Chronic Constipation (HUM9070)

Principal Investigator: Richard Saad, Pager #14066

Study Coordinator: Borko Nojkov, Pager #30646, 734-936-8750, bnojkov@med.umich.edu

Study Title:

A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Dose-Range-Finding, Parallel-Group, Phase 2 Trial of Oral Linaclotide Acetate Administered to Patients with Chronic Constipation”

Study purpose:

To determine the safety, efficacy, and dose response of a range of oral doses of linaclotide administered as oral capsules to patients meeting criteria for chronic constipation.

Study Design:

Phase II, multicenter, to enroll 300 patients nationwide, 5 from UMHS
5 visits over a span of 8-12 weeks, with 4 weeks of treatment phase. Drug dosing is placebo, 75, 150, 300, or 600ug linaclotide. Study procedures include: physical exam, ECG, and clinical lab testing.

Eligibility:

- Male and female ages 18 and older
- Fulfilling criteria for chronic constipation (<3 BMs per week plus one or more of the following: straining >25%. hard stool >25%, or sensation of incomplete evacuation).
- Meets colonoscopy requirements of American Gastroenterological Assoc. Guidelines
- No history of surgeries or malignancies to the gastrointestinal system.