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Trial record **1 of 1** for: NCT02008565

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Controlling Anal Incontinence by Performing Anal Exercises With Biofeedback or Loperamide (CAPABLe) (CAPABLe)

This study is ongoing, but not recruiting participants.

Sponsor:
NICHD Pelvic Floor Disorders Network

Collaborators:
The Cleveland Clinic
University of Alabama at Birmingham
University of California, San Diego
Duke University
National Institutes of Health (NIH)
University of New Mexico
Women and Infants Hospital of Rhode Island
RTI International
University of Pennsylvania
University of Pittsburgh
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Information provided by (Responsible Party):
NICHD Pelvic Floor Disorders Network

ClinicalTrials.gov Identifier:
NCT02008565

First received: December 6, 2013
Last updated: March 24, 2016
Last verified: March 2016
History of Changes

Full Text View | **Tabular View** | **No Study Results Posted** | Disclaimer | How to Read a Study Record

Purpose

The study is a multi-center, randomized, placebo controlled trial with participants randomized into one of four groups:

1. placebo/usual care (educational pamphlet)
2. loperamide/usual care (educational pamphlet)
3. placebo/anal exercises with biofeedback
4. loperamide/anal exercises with biofeedback

The primary outcome, change from baseline in St. Marks (Vaizey) Score at 24 weeks, will be compared between treatment groups using linear regression.

Condition	Intervention	Phase
Fecal Incontinence	Drug: Loperamide Drug: Placebo Behavioral: Anal exercises with biofeedback Behavioral: Usual Care	Phase 3

Study Type: Interventional

Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Factorial Assignment
Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Controlling Anal Incontinence by Performing Anal Exercises With Biofeedback or Loperamide (CAPABLe): a Randomized Placebo Controlled Trial

Resource links provided by NLM:

MedlinePlus related topics: Bowel Movement Exercise and Physical Fitness

Drug Information available for: Loperamide hydrochloride

U.S. FDA Resources

Further study details as provided by NICHD Pelvic Floor Disorders Network:

Primary Outcome Measures:

- Change from baseline St. Mark's (Vaizey) Score [Time Frame: 24 week visit] [Designated as safety issue: No]

  The primary outcome measure for all study arms is the change from baseline in St. Mark's (Vaizey) Score 24 weeks after treatment initiation to compare the marginal outcomes of anal exercise with biofeedback to usual care and loperamide to placebo.

Secondary Outcome Measures:

- Condition-specific and generalized quality of life [Time Frame: 12 and 24 week visits] [Designated as safety issue: No]

  Change in quality of life between those randomized to loperamide compared to placebo and between those randomized to anal sphincter exercises with biofeedback compared to usual care (educational pamphlet).

- Efficacy Measures [Time Frame: 12 and 24 week visits] [Designated as safety issue: No]

  Measures of efficacy include bowel diary measures, digital rectal tone, and anal manometry measures .

- Patient satisfaction [Time Frame: 12 and 24 week visits] [Designated as safety issue: No]

  Participants' satisfaction with FI treatment modality defined as a response that their condition is "much better" or "very much better" on the PGI-I.

- Cost-effectiveness of FI treatment [Time Frame: 12 and 24 week visits] [Designated as safety issue: No]

  Cos-effectiveness of FI treatment modalities will be assessed using the patient's and societal perspectives.

- Succes of masking the drug treatment arm [Time Frame: 24 week visit] [Designated as safety issue: No]

  The purpose of this outcome is to assess the extent to which masking of the drug treatment arm is successful with respect to both the patient and the study coordinator.

Estimated Enrollment:	294
Study Start Date:	February 2014

Estimated Study Completion Date: September 2016
Estimated Primary Completion Date: April 2016 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Placebo Comparator: Placebo Placebo doses range from 2mg every other day to 8mg per day. Capsules are taken by mouth once a day for 24 weeks.	Drug: Placebo Participants randomized to the placebo arm will begin the a dose of one capsule per day and will be dose increased or dose decreased using the same algorithm described for the loperamide arm. Other Name: Inactive Drug
Experimental: Anal exercises with biofeedback Six sessions with trained personnel will occur every 2 weeks over a 12-week period. Sessions will be held at the following study visits: baseline, 2, 4, 6, 9, and 12 week visits.	Behavioral: Anal exercises with biofeedback Participants will receive a formal anal exercises training program that can be easily applied in an office setting with minimal participant burden. Participants will attend six anal exercises with biofeedback sessions with trained personnel over a 12-week period for the 24-week study. Sessions will include introduction, standard patient education, and exercises using anal manometry-assisted biofeedback introducing concepts such as shaping, generalization and termination. The protocol uses strength and sensory training including urge resistance training. During the final twelve weeks, participants will perform anal exercises on their own. The sessions with interventionists will occur every other week for 12 weeks (total 6 supervised sessions).
Placebo Comparator: Usual care Participants will receive education and a NIDDK Bowel Control Educational pamphlet	Behavioral: Usual Care Usual care consists of patients receiving an educational pamphlet on fecal incontinence created by the National Institute of Diabetes and Digestive and Kidney Diseases.
Experimental: Loperamide Loperamide doses range from 2mg every other day to 8mg per day. Capsules are taken by mouth once a day for 24 weeks.	Drug: Loperamide Participants randomized to the loperamide group will begin with 2mg of loperamide/day. The participant will be administered the Patient Global Symptom Control rating scale (PGSC) to determine dose escalation. Participants who report inadequate control of stool leakage on the PGSC will be instructed to increase the daily dose of loperamide by 2 mg up to a maximum of 8 mg per day (1-4 capsules). Bothersome adverse events and resulting dose reduction will be based exclusively on the result of the Patient Global Tolerability Scale (PGTS). The daily dose will be decreased by 2mg to a minimum of 2mg every other day. If a PGSC score indicates inadequate control of stool leakage combined with a PGTS score indicating bothersome side effects, the participant will discontinue the study medication. Other Name: Imodium

Detailed Description:

The goals of this trial are to compare the use of loperamide to oral placebo and to compare the use of anal sphincter exercise training with biofeedback to usual care (educational pamphlet) in the treatment of women suffering from fecal incontinence (FI). We will test the following null hypotheses:

1. there is no difference in outcomes between women randomized to loperamide and women randomized to oral placebo for treatment of FI;
2. there is no difference in outcomes between women randomized to anal sphincter exercises with biofeedback and women randomized to usual care (educational pamphlet) for FI treatment;
3. there is no difference between women randomized to both treatments together and women randomized to either FI treatment alone; and
4. there is no correlation between anal manometry measurements and digital anal squeeze strength or measures of FI severity and bother.

A supplemental study, Stool Metabolome and Microbiome in Women with Fecal Incontinence in CAPABLe, will evaluate the stool metabolome and microbiome in women with fecal incontinence and unaffected age matched controls.

Eligibility

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Genders Eligible for Study:	Female
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Age ≥18 years
- Fecal incontinence defined as any uncontrolled loss of liquid or solid fecal material that occurs at least monthly over the last 3 months that is bothersome enough to desire treatment

Exclusion Criteria:

- Stool consistency over the last 3 months that includes items 1 or 7 based on the Bristol Stool form scale
- Current or past diagnosis of colorectal or anal malignancy
- Diagnosis of inflammatory bowel disease
- Current or history of rectovaginal fistula or cloacal defect
- Rectal prolapse (mucosal or full thickness)
- Prior removal or diversion of any portion of colon or rectum

- Prior pelvic floor or abdominal radiation
- Refusal or inability to provide written consent
- Inability to conduct telephone interviews conducted in English or Spanish
- Fecal impaction by exam
- Untreated pelvic organ prolapse beyond the hymen; Patients with prolapse beyond the hymen who are currently using a pessary are eligible
- Incontinence only to flatus
- Has taken any loperamide (Imodium®) or diphenoxylate plus atropine (Lomotil®) in the last 30 days
- Previously received and failed treatment of fecal incontinence using loperamide (Imodium®) or diphenoxylate plus atropine (Lomotil®) over the last 3 months
- Current supervised anal sphincter exercise/pelvic floor muscle training with biofeedback
- Previously received and failed treatment of fecal incontinence using supervised anal sphincter exercise/pelvic floor muscle training with biofeedback
- Previous allergy or intolerance to loperamide
- Pregnant, nursing, or planning to become pregnant before the end of the study follow-up period.
- Childbirth within the last 3 months
- Currently taking anti-retroviral drugs
- Neurological disorders known to affect continence, including spinal cord injury, advanced multiple sclerosis or Parkinson's disease and debilitating stroke
- Known diagnosis of hepatic impairment
- Chronic abdominal pain in the absence of diarrhea

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: NCT02008565

Locations

United States, Alabama

University of Alabama at Birmingham
Birmingham, Alabama, United States, 35233

United States, California

University of California at San Diego
La Jolla, California, United States, 92037-0974

Kaiser San Diego
San Diego, California, United States, 92110

United States, New Mexico

University of New Mexico
Albuquerque, New Mexico, United States, 87131

United States, North Carolina

Duke University
Durham, North Carolina, United States, 27707

United States, Ohio

Cleveland Clinic
Cleveland, Ohio, United States, 44195

United States, Pennsylvania

University of Pennsylvania
Philadelphia, Pennsylvania, United States, 19118

University of Pittsburgh
Pittsburgh, Pennsylvania, United States, 15213

United States, Rhode Island

Brown/Women and Infants Hospital of Rhode Island
Providence, Rhode Island, United States, 02903

Sponsors and Collaborators

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University of New Mexico

Women and Infants Hospital of Rhode Island

RTI International

University of Pennsylvania

University of Pittsburgh

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Investigators

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More Information

Responsible Party: NICHD Pelvic Floor Disorders Network
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Individual Participant Data Plan to Share IPD: No

Keywords provided by NICHD Pelvic Floor Disorders Network:
Fecal incontinence
Loperamide

anal exercises
biofeedback

Additional relevant MeSH terms:

Fecal Incontinence	Digestive System Diseases
Rectal Diseases	Loperamide
Intestinal Diseases	Antidiarrheals
Gastrointestinal Diseases	Gastrointestinal Agents

ClinicalTrials.gov processed this record on July 18, 2016