Effects of Ondansetron on Gastrointestinal Sensorimotor Dysfunctions in Diabetes Mellitus and Dyspepsia

NCT03865290

Status	RECRUITING
Phase	Phase 2
Sponsor	Mayo Clinic
Enrollment	150 participants

Key Eligibility Criteria

Inclusion (6)

- Healthy male or non-pregnant, non-breastfeeding female volunteers;
- years old;
- Able to provide written informed consent before participating in the study
- Able to communicate adequately with the investigator and to comply with the requirements for the entire study; including the willingness and ability to consume the components of the test meals
- Symptoms of dyspepsia (i.e., early satiety, postprandial discomfort, nausea, vomiting, regurgitation)

... and 1 more (see full listing online)

Exclusion (15)

- Major abdominal surgery (i.e., appendectomy, cholecystectomy, tubal ligation, hysterectomy, herniorrhaphy, and limited colonic resection are permissible)
- Clinical evidence (including physical exam and EKG) of significant cardiovascular, respiratory, renal, hepatic, gastrointestinal, hematological, neurological, psychiatric or other disease that may interfere with the objectives of the study and/or pose safety concerns
- Current use of opiates, alpha adrenergic agonists, metoclopramide, monoamine oxidase inhibitors, more than one serotonergic medication, and high doses of anticholinergic agents (eg, amitriptyline greater than 50 mg daily). If medically safe, these drugs may be discontinued for four half lives prior to study assessments.
- Treatment with GLP-1 agonists and amlyin which cause vagal blockade and may affect central processing of pain
- Bleeding or clotting disorders or medications that increase risk of bleeding from mucosal biopsies

... and 10 more (see full listing online)

Locations (1 total)

Mayo Clinic in Rochester, Rochester, Minnesota, United States