

Domperidone in Treating Patients With Gastrointestinal Disorders

NCT01696734

Status	RECRUITING
Phase	Phase 3
Sponsor	M.D. Anderson Cancer Center
Enrollment	200 participants

Key Eligibility Criteria

Inclusion (14)

- Patients with GI disorders who have failed standard therapy
 - Symptoms or manifestations of: a) gastroparesis; b) refractory gastroesophageal reflux disease (GERD) including persistent esophagitis, refractory heartburn, reflux-related laryngitis, and respiratory symptoms; or c) severe dyspepsia
 - Completion of a comprehensive evaluation, including clinical history and physical examination, to eliminate other causes of their symptoms
 - Patient has signed the informed consent document agreeing to the use of the study drug, domperidone
 - White blood cell (WBC) with differential greater than 3,000/ml
- ... and 9 more (see full listing online)

Exclusion (9)

- Patients with the following cardiac diagnoses: ventricular tachycardia or fibrillation; Torsade des Pointes; clinically significant bradycardia; sinus node dysfunction; heart block; prolonged QTc interval (QTc $>$ 450 milliseconds for males, QTc $>$ 470 milliseconds for females); prior specific cardiovascular conditions of clinically significant valvular heart disease requiring medication, ischemic, or pulmonary heart disease; cardiomyopathy; history of heart failure
 - Patients who are receiving antiarrhythmic medications with action on repolarization times (with prolongation of the QTc interval such as amiodarone, disopyramide, dofetilide, flecainide, ibutilide, quinidine, sotalol, dronedarone etc.)
 - Patients who are receiving monoamine oxidase (MAO) inhibitors
 - Patients with a history of or active liver failure
 - Clinically significant electrolyte disorders including sodium $<$ 130 or $>$ 145 and/or potassium $<$ 3.0 or $>$ 5.5 and/or magnesium $<$ 1.6 or $>$ 2.6
- ... and 4 more (see full listing online)

Locations (1 total)

M D Anderson Cancer Center, Houston, Texas, United States

<https://clinicaltrials.gov/study/NCT01696734>

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