

Chronic Nausea and Vomiting in Patients With Normal Gastric Emptying Using the Enterra® Therapy System (NAVIGATE)

NCT06464926

Status	RECRUITING
Phase	Not Applicable
Sponsor	Enterra Medical, Inc.
Enrollment	148 participants

Key Eligibility Criteria

Inclusion (9)

- Willing and able to complete the informed consent process
- Stated willingness to comply with all study procedures and availability for the duration of the study
- Aged ≥18 years at time of informed consent
- Chronic, drug-refractory nausea that: a) has been present for more than 6 months, and b) has been active within the last 3 months prior to consent
- Patient is able to complete ANMS GCSI-DD surveys on a compatible smart device with: a) a minimum of four (4) ANMS GCSI-DD entries per week for two consecutive weeks, and b) an average ANMS GCSI-DD score for nausea severity of ≥2.5 during the same two-week period

... and 4 more (see full listing online)

Exclusion (35)

- Cognitive impairment or other characteristic that would limit a patient's ability to complete study requirements
- Pyloric transection therapy completed within 1 year of consent
- Documented gastrointestinal (GI) obstruction or pseudo-obstruction
- History of primary swallowing disorders
- History of primary psychogenic vomiting

... and 30 more (see full listing online)

Locations (17 total)

Mayo Clinic Arizona, Scottsdale, Arizona, United States
Hoag Hospital, Newport Beach, California, United States
Sutter Health, San Francisco, California, United States

... and 14 more locations