Randomized Trial of UI-EWD vs. Conventional Endoscopic Therapy for Nonvariceal Upper Gastrointestinal Bleeding

NCT06188585

Status	RECRUITING
Phase	Not Applicable
Sponsor	Medtronic - MITG
Enrollment	278 participants

Key Eligibility Criteria

Inclusion (4)

- Adults age 22 years or older
- Presentation with acute overt gastrointestinal bleeding (hematemesis, melena, and/or hematochezia)
- Subject voluntarily agrees to participate in the clinical investigation, provides written informed consent, and will be able to comply with the investigational protocol in the opinion of the site investigator
- Cause of bleeding as determined at upper endoscopy is one of the following sources: a gastric or duodenal ulcer with active bleeding (spurting or oozing) or a non-bleeding visible vessel; an esophageal, gastric or duodenal tumor with active bleeding or a non-bleeding visible vessel; a gastric or duodenal Dieulafoy lesion with active bleeding or a non-bleeding visible vessel; or an actively bleeding Mallory-Weiss tear. The definition of "active oozing" will require bleeding to persist for e 3 minutes of endoscopic observation.

Exclusion (14)

- Incarceration
- Subjects that are not able to provide written informed consent
- Pregnancy or nursing mothers
- Endoscopic hemostatic treatment in the past 30 days
- Use of triple antithrombotic therapy at the time of presentation

... and 9 more (see full listing online)

Locations (15 total)

University of Alabama, Birmingham, Alabama, United States
Yale, New Haven, Connecticut, United States
RUSH University, Chicago, Illinois, United States
... and 12 more locations