Endoscopic ultrasonography-guided gastroenterostomy versus surgical gastrojejunostomy for palliation of malignant gastric outlet obstruction (ENDURO-study)

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Primary objective:to investigate and compare the effect of EUS-GE and SGJ on patients* short- and long-term ability to eat* (time to oral intake, and reinterventions for persistent or recurrent symptoms of GOO within 6 months of follow-up,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Interventional

Summary

ID

NL-OMON54213

Source
ToetsingOnline

Brief title
ENDURO-study

Condition

- Gastrointestinal stenosis and obstruction

Synonym
Malignant gastric outlet obstruction, Malignant GOO

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: Malignant gastric outlet obstruction, Surgical gastrojejunostomy, Ultrasonography-guided gastroenterostomy

Outcome measures

Primary outcome

The main study endpoint is the ability to eat, measured with co-primary

endpoints: 1) time to oral intake, and 2) persistent or recurrent gastric

outlet obstruction (GOO) symptoms requiring endoscopic or surgical

reintervention.

Secondary outcome

- Technical success;

- Clinical success;

- Gastroenterostomy dysfunction;

- Reintervention;

- Time to reintervention due to recurrent symptoms;

- Adverse events; .

- Quality of life;

- Time to start chemotherapy;

- Length of hospital stay;

- Readmission rate;

- Weight is defined as patients* weight in kilograms;

- Survival;

- Costs.

Study description

Background summary

Malignant gastric outlet obstruction (GOO) is a common problem in patients with advanced primary or metastatic malignancy located at the distal stomach and (peri)pancreatic region. With a reasonable life expectancy, surgical gastrojejunostomy (SGJ) is indicated to bypass this obstruction and palliate obstructive symptoms. Despite high technical success rates and a durable effect, SGJ is an invasive treatment that is associated with significant short-term morbidity, such as gastroparesis, resulting in an ongoing inability to eat and prolonged hospital stay. Endoscopic ultrasonography-guided gastroenterostomy (EUS-GE) using a Lumen Apposing Metal Stent (LAMS) is the newest technique in the palliative treatment of malignant GOO. EUS-GE creates a bypass in a minimally invasive manner, with the potential of providing both fast and lasting relief of obstructive symptoms. Despite promising preliminary data, current literature is limited to small and retrospective series. A prospective and comparative study is warranted, to compare short and long term efficacy of EUS-GE with SGJ.

Study objective

Primary objective:
to investigate and compare the effect of EUS-GE and SGJ on patients* short- and long-term ability to eat* (time to oral intake, and reinterventions for persistent or recurrent symptoms of GOO within 6 months of follow-up, respectively)

Secondary objectives/questions:
- What is the technical success rate of EUS-GE vs SGJ?
- What is the clinical success rate of EUS-GE vs SGJ?
- What is the rate of gastroenterostomy dysfunction of EUS-GE vs SGJ?
- What is the reintervention rate of EUS-GE vs SGJ?
- What is the time to reintervention in case of recurrent symptoms after EUS-GE vs SGJ?
- What is the adverse events rate of EUS-GE vs SGJ?
- What is the effect of EUS-GE vs SGJ on the quality of life?
- What is the time to start chemotherapy (if applicable) after EUS-GE vs SGJ?
- What is the length of hospital stay of EUS-GE vs SGJ?
- What is the rate of readmissions after EUS-GE vs SGJ?
- What is the patients* weight after EUS-GE vs SGJ (baseline vs one month after treatment)?

- What is the overall survival time after EUS-GE vs SGJ?
- What are the costs involved in EUS-GE vs SGJ?

Study design

National multicenter study
Randomized controlled trial

Intervention

After randomization, one group will receive the standard treatment (surgical gastrojejunostomy; SGJ), the other group will receive the experimental treatment (endoscopic ultrasonography-guided gastroenterostomy; EUS-GE)

Study burden and risks

The burden and risks of EUS-GE are expected to be lower than those of the standard treatment (SGJ). Participation in this therapeutic study offers patients with malignant GOO the opportunity to undergo EUS-GE, an investigational and minimally invasive treatment, instead of surgery. No additional visits or physical examinations are required for this study, unless medically indicated. The burden of follow-up within this study is limited and mainly concerns time that is spent to fill in the diary, short quality-of-life questionnaires and receive four short follow-up phone calls. Though the short-term results of EUS-GE are promising and seem to be beneficial, the long-term patency of EUS-GE has yet to be established and compared with the current standard treatment (SGJ). This can only adequately be achieved by comparing the efficacy of EUS-GE versus SGJ in these patients, in a randomized and prospective study with solid follow-up.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Adult patients with symptomatic malignant gastric outlet obstruction, presenting with nausea, vomiting and/or inability to eat
- Gastric Outlet Obstruction Scoring System Score of 0 (no oral intake) or 1 (liquids only)
- Obstruction due to irresectable or metastatic malignancy without curative treatment options
- Radiologically or endoscopically confirmed gastric outlet obstruction
- Location of obstruction extending from the distal 1/3 of the stomach (antrum) to the distal duodenum (third part)
- Both treatments (SGJ and EUS-GE) are technically and clinically feasible
- Written informed consent

Exclusion criteria

- Radiological or clinical suspicion of other strictures or obstructions along the gastrointestinal tract (distal of Treitz), with small intestine intestinal dilation/ileus. Note: patients with diffuse dilatation of the intestines should not be excluded;
- Cancer extending into the body of the stomach or around the ligament of Treitz;
- Duodenal tube feeding is not tolerated by the patient, despite adequate position of the tube;
- Altered anatomy after previous gastric, periampullary or duodenal surgery;
- Previous SGJ as palliative treatment for the same condition;
- Inability to undergo surgery or upper endoscopy due to severe comorbidities;
- WHO performance score of 4 (in bed 100% of time);

- Uncorrectable coagulopathy, defined by INR>1.5 or platelets < 50 x 10^9/L;

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-02-2022
Enrollment:	96
Type:	Actual

Medical products/devices used

Generic name:	Hot AXIOS stent & electrocautery-enhanced delivery system
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	18-11-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	08-02-2022
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO Date:	08-08-2023
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25505
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL77548.041.21
Other	NL9592
OMON	NL-OMON25505