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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25505

Source
Nationaal Trial Register

Brief title
ENDURO

Health condition

Malignant gastric outlet obstruction

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Outcome measures

Primary outcome

Our main study parameter is the ability to eat. This will be measured with two co-primary endpoints, covering the short- and long-term effects:

1a. Time to oral intake of soft solids is defined as the number of days until a patient is able to tolerate soft solids (GOOSS ≥ 2) without vomiting. Day of intervention is considered day 0.
1b. Persistent or recurrent GOO symptoms requiring reintervention is defined as any new intervention after EUS-GE or SGJ directed at improving or restoring nutritional intake, in case of persistent or recurrent obstructive symptoms of gastric outlet obstruction, such as nausea, vomiting or inability to tolerate oral intake (GOOSS 0-1).

Secondary outcome

Our secondary endpoints are defined as follows:
2. Technical success is defined as successful creation of a gastroenterostomy by means of the allocated technique (EUS-GE or SGJ). Successful (stent-in-stent) placement of a second Hot AXIOS stent during the same procedure after the initial attempt failed is also considered technically successful. If additional techniques, modalities or different type of stents (e.g. self-expandable metallic stents) were required, it will be regarded as technical failure.
3. Clinical success is defined as relief of symptoms and toleration of soft solids (GOOSS ≥2) without vomiting.
4. Gastroenterostomy dysfunction is defined as recurrence of obstructive symptoms (GOOSS 0-1) due to recurrence of GOO at the gastroenterostomy site after initial clinical success, confirmed endoscopically or radiographically.
5. Reintervention is defined as any endoscopic or surgical intervention for an adverse event, persistent obstructive symptoms or recurrent obstructive symptoms, that is needed after EUS-GE or SGJ. This includes creating an alternative route to improve or restore adequate nutritional intake – either through placing a nasal feeding tube, construction of a gastrostomy or jejunostomy, or through initiating parenteral nutrition.
6. Time to reintervention for recurrence of symptoms is defined as the time in days between EUS-GE/SGJ and reintervention for recurrence of symptoms of GOO (nausea, vomiting, inability to tolerate oral intake).
7. Adverse events are specified according to the ASGE lexicon for endoscopic adverse events. An adverse event is defined as “an event that prevents completion of the planned procedure and/or results in admission to hospital, prolongation of existing hospital stay, another procedure (needing sedation/anesthesia), or subsequent medical consultation.”30 Late adverse events are considered events occurring beyond thirty days after the study procedure. Severity of adverse events is graded according to the Clavien-Dindo Complication Score (severe is defined as ≥ 3B).31,32
Common or expected AEs are the following: abdominal pain, bleeding, perforation, anastomotic leakage, peritonitis.23,33 For more detailed information, see 9.2 AEs, SAEs and SUSARs
8. Quality of life will be measured by 2 cancer specific questionnaires (core-questionnaire EORTC QLQC30 supplemented with a disease-specific module EORTC QLQ-STO22 focusing on gastric complaints) to measure health related quality of life of cancer patients and to compute quality-adjusted life years (QALYs).
9. Time to start chemotherapy is defined as the number of days after EUS-GE/SGJ until chemotherapy is started (if applicable).

10. Length of hospital stay is defined as days of hospitalization between EUS-GE/SGJ and hospital discharge. If patients are transferred back to a referring hospital, the final date of discharge from their referring hospital will be registered.
11. Readmission: number and duration of hospital readmissions within 30 days after EUS-GE/SGJ.
11. Weight is defined as patients' weight in kilograms. Comparison is made between weight at baseline and weight one month after EUS-GE/SGJ.
12. Survival is defined by the number of days after EUS-GE/SGJ until death. The cause of death will be registered.
13. Costs are defined as the intramural costs that were involved with EUS-GE/SGJ, collected from the electronic hospital records and linked to the Dutch unit costs. Primary outcome measures from our economic evaluation are Quality Adjusted Life Years (QALY) and Incremental Cost Effectiveness Ratios (ICERs).

Study description

Background summary

Rationale: Malignant gastric outlet obstruction (GOO) is a common problem in patients with advanced primary or metastatic malignancies located at the distal stomach and (peri)pancreatic region. The two standard methods of treating GOO are placement of an enteral self-expendable metallic stent (SEMS) or a surgical gastrojejunostomy (SGJ). In patients with a reasonable prognosis, placement of an enteral SEMS is not feasible since it carries high rates of reobstruction or stent migration after a certain amount of time. Therefore, in these patients, surgical gastrojejunostomy 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 delayed gastric emptying, resulting in an ongoing inability to eat and a 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.

Objective: To evaluate the efficacy of EUS-GE compared with SGJ in patients with malignant GOO.

Study design: Randomized Controlled Trial

Study population: Adult patients with a malignant gastric outlet obstruction due to locally advanced or metastatic, inoperable and unresectable cancer, without curative options.

Intervention: One group will be treated with the standard treatment (SGJ) and the other

group will be treated with the investigational treatment (EUS-GE with LAMS [off label use]).

Main study parameters/endpoints: The main study endpoint is the ability to eat, measured with co-primary endpoints: 1) time to oral intake, and 2) persistent or recurrent GOO symptoms requiring reintervention.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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 a 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.

Study objective

It is hypothesized that patients with malignant gastric outlet obstruction after having undergone an endoscopic ultrasound-guided gastroenterostomy will faster resume oral intake and have a similar adverse event risk profile as compared to a surgical gastrojejunostomy.

Study design

Four moments of telephonic contact in six months of follow-up

Intervention

EUS-guided gastroenterostomy versus surgical gastrojejunostomy

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible for this study, a subject must meet all of the following 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 pyloric region 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 the ligament of Treitz), with small intestinal dilation/ileus. Note: patients with diffuse dilatation of the intestines should not be excluded;
- Cancer extending into the distal region or corpus of the stomach or around the ligament of Treitz. These types may pose a risk of negatively affecting gastrointestinal motility next to causing gastric outlet obstruction.
- Duodenal tube feeding is not tolerated, 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 (including large-volume ascites);
- WHO performance score of 4 (in bed 100% of time);
- Uncorrectable coagulopathy, defined by INR > 1.5 or platelets < 50 x 109/L;

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2022
Enrollment:	96
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
Deidentified individual participant-level data will be shared through the electronic data capture tool Castor. In this database, merely deidentified patient data will be saved, untraceable to specific persons.

Ethics review

Positive opinion

Date:	07-07-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54213
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9592
CCMO	NL77548.041.21
OMON	NL-OMON54213

Study results

Summary results
None