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

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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…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25505

Bron
Nationaal Trial Register

Verkorte titel
ENDURO

Aandoening

Malignant gastric outlet obstruction

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: KWF Kankerbestrijding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

EUS-guided gastroenterostomy versus surgical gastrojejunostomy

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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;

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2022
Aantal proefpersonen:	96
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
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.

Ethische beoordeling

Positief advies

Datum:	07-07-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54213

Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
None