

# 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,...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Gastrointestinal stenosis and obstruction
<b>Study type</b>	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<sup>9</sup>/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: NTR  
Title:

### In other registers

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