Treatment outcome of Gastric Peroral Endoscopic Pyloromyotomy in comparison with Percutaneous Endoscopic Gastrostomy with Jejunal extension in medically refractory gastroparesis: a prospective randomized controlled trial.

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Primary objective:To investigate the treatment success using the GCSI-score in patients with refractory GP undergoing G-POEM compared to patients receiving a PEG-J at t = 6 months.Secondary objectives:1. To investigate the treatment success using...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON56563

Source
ToetsingOnline

Brief title
G-POEM vs PEG-J for refractory gastroparesis

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Gastroparese, GP

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Gastroparesis, G-POEM (gastric peroral endoscopic pyloromyotomy), Motility disorder, PEG-J (percutaneous endoscopic gastrostomy with jejunal extension)

Outcome measures

Primary outcome

A clinically meaningful treatment success six months after G-POEM treatment,

measured using the GCSI-score defined as a decrease of 1 point or more.

Secondary outcome

- A clinically meaningful treatment success twelve months after G-POEM

treatment, measured using the GCSI defined as a decrease of >= 1 point, measured

as a difference between GCSI at t=0 vs t=12 months after intervention.

- Quality of life six months after treatment using the PAGI-QOL compared to

baseline and 3 month after treatment, determined as the difference between t =

0 months vs t = 3 months and t = 6 months after intervention.

- Number and severity of (s)AEs

- Etiology characteristics predictive for treatment success after G-POEM.

- Etiology characteristics predictive for treatment success after PEG-J.

- A clinically meaningful treatment success six months after G-POEM

intervention, measured using the modified GCSI (exclusion of question 5 and 6)

defined as a decrease of 1 point or more, measured as a difference between GCSI

at t = 0 months vs t = 3 month and t = 6 months after intervention.

- To investigate predictors for treatment success 6 months after G-POEM by

means of Body Surface Gastric Mapping (BSGM) with the Gastric Alimetry system.

Study description

Background summary

Gastroparesis (GP) is a gastric motility disorder consisting of upper abdominal complaints and delayed gastric emptying where mechanical obstruction is excluded. It is a multifactorial disease with a high severity of impairment and the complete pathophysiology is not fully understood. Gastric hypomotility and an increased pyloric tone are mentioned as important underlying mechanisms. In the MUMC+, tertiary referral centre for GP patients, treatment is based on a stepwise approach starting with dietary advices, prokinetics and in some cases tube feeding for three months (gastric rest) in case of decompensated GP. When reintroduction of oral intake fails, long-term nutritional support is offered by placement of a percutaneous endoscopic gastrostomy with jejunal extension (PEG-J). PEG-J is a well-established therapy for gastroparesis. An advantage of this PEG-J is that adequate intake is guaranteed. Disadvantages are that patients have a tube through the abdominal wall and oral intake cannot be resumed. Especially, for the latter reason there is a need for a technique in which the oral intake can be resumed immediately. Recent literature showed promising results for the gastric peroral endoscopic pyloromyotomy (G-POEM). This is a new pylorus-directed minimally invasive therapy consisting of purely endoscopic myotomy. Studies showed a treatment success of 71% and 77% after six months and 48 months of follow-up, respectively. Lowering the pyloric tone should improve the passage of food. This treatment can therefore lead to a resumption of intake immediately after intervention. Considering the promising results and benefits regarding resumption of intake, opportunities are seen for standard treatment in refractory GP patients in order to circumvent the disadvantages of a PEG-J.

Study objective

Primary objective:
To investigate the treatment success using the GCSI-score in patients with refractory GP undergoing G-POEM compared to patients receiving a PEG-J at t = 6 months.

Secondary objectives:
1. To investigate the treatment success using the GCSI-score in patients with

refractory GP undergoing G-POEM compared to patients receiving a PEG-J at t=12 months.
2. To assess the quality of life using the PAGI-QOL in the G-POEM group in comparison with the PEG-J intervention group.
3. To measure frequency and severity of (s)AEs in the treatment groups.
4. To evaluate whether the etiology of GP can be predictive of treatment success after G-POEM.
5. To evaluate whether the etiology of GP can be predictive of treatment success after PEG-J.
6. To identify predictors of short- and long-term G-POEM success (defined as at least one point decrease in the GCSI-score at 6 months) measured by the Gastric Alimetry system.

Sensitivity analysis:
1. To investigate the treatment success using the modified GCSI (exclusion of questions 5 and 6) in patients with refractory GP undergoing G-POEM compared to patients receiving a PEG-J at t = 6 months.

Study design

A randomized non-blinded controlled clinical trial with two study arms (G-POEM and PEG-J). Treatment success is measured using the GCSI at baseline before intervention and six months after intervention with a possible cross-over after six months of follow-up.

Intervention

Group 1 will receive G-POEM treatment and group 2 will receive PEG-J treatment.

Study burden and risks

This study does not involve any incapacitated or minority groups and is considered a low-risk study.
Both study groups will benefit equally by participating in this study. Both treatments have there own advantages and disadvantages. An advantage of the PEG-J procedure is that nutritional status can be immediately controlled and it is a minimal invasive therapy. A disadvantage is that patients can not resume oral intake after treatment. A risk of the therapy is infection, perforation or displacement of the tube which requires repositioning or replacement.
An advantage of the G-POEM procedure is that it is a minimal invasive therapy and it is possible to resume oral intake immediately after treatment. A risk of the therapy is that perforation can occur or rectal bleeding.
The cross-over design gives every participant the opportunity to receive the treatment they not primarily got. At the end of the study all participants benefit equally.

In terms of burden, participation is nearly identical for both groups as they complete the same questionnaires at the same intervals. Given the nature and time investment required to complete these questionnaires, this is considered non-burdensome. In case of the G-POEM intervention, an additional time investment of 4.5 hours will be required for the Gastric Alimetry measurement. However, efforts will be made to combine this with other hospital appointments.

In conclusion, the risks associated with participation in the study are proportional to the benefits that subjects may experience.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229 ER
NL
Scientific
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients with therapy refractory gastroparesis

- 13C octanoic acid test or gastric scintigraphy (minimal 4-hour measurement) within the past twelve months
- >= 18 years old

Exclusion criteria

- < 18 years old
- Medical history of stomach surgery in which resection of antrum and/ or pylorus took place
- Medical history of surgical or laparoscopic pyloromyotomy
- Gastric bypass
- Current opioid use
- Pregnancy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-03-2024
Enrollment:	50
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	01-02-2024
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-01-2025
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL85305.068.23