

Endoscopic Stenting versus Operative Intervention in Malignant Gastric Outlet Obstruction(STENTOP), a multi-center randomized controlled trial.

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To investigate which treatment modality is preferable in patients with an irresectable malignant gastric outlet obstruction: endoscopic stent placement or a surgical gastrojejunostomy.

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

Summary

ID

NL-OMON35111

Source

ToetsingOnline

Brief title

STENTOP

Condition

- Gastrointestinal stenosis and obstruction
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym

Malignant gastric outlet obstruction

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Gastrojejunostomy, Malignant gastric outlet obstruction, Self-expandable metal stent

Outcome measures

Primary outcome

Percentage of days alive within the first 24 weeks after intervention with an oral intake of at least soft solids (GOOSS ≥ 2)

Secondary outcome

Gut Function Score (GFS), technical success, length of procedure-related hospital stay, complication rate (including pain intensity using a numerical rating scale, NRS), recurrent obstruction and reintervention rate, quality of life (QoL), costs and survival.

Study description

Background summary

Malignant gastric outlet obstruction is a late complication in patients with primary gastric or periampullary malignancy or metastatic disease. Palliation of obstructive symptoms is essential in these patients. Surgical gastrojejunostomy as well as endoscopic stent placement can be performed. At this moment there isn't a definite scientific based rationale to favor one over the other with respect to efficacy, complications, quality of life and costs.

Study objective

To investigate which treatment modality is preferable in patients with an irresectable malignant gastric outlet obstruction: endoscopic stent placement

or a surgical gastrojejunostomy.

Study design

Prospective, multi-center randomized controlled study with a follow-up of 24 weeks.

Intervention

In one treatment group a Self Expandable Metal Stent (SEMS) will be used. In the other treatment group an open or laparoscopic gastrojejunostomy will be performed.

Study burden and risks

Patients will be contacted by telephone at regular intervals for assessing questionnaires. Also, during the first 3 weeks patients will be asked to fill in a symptom-diary. In our opinion this will not put burden on patients significantly.

The randomisation between endoscopic stent placement and surgical intervention will not expose patients to additional risks. Initially, stent placement seems to be a less invasive procedure. However, recent studies demonstrate that on the long term stent placement may be complicated with a higher rate reobstruction and reintervention. Thus, at this moment it is unclear which treatment modality is preferable with respect to risks and complications.

Contacts

Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
3015 CE Rotterdam
NL

Scientific

Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
3015 CE Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Malignancy of peri-duodenal area

Gastric Outlet Obstruction Scoring System (GOOSS) ≤ 1

Life expectancy ≥ 4 weeks

Informed consent

Age ≥ 18 years

Exclusion criteria

Potentially curable disease

Pre-procedural evidence of additional strictures in the gastrointestinal tract beyond the level of the duodenum

Previous gastrojejunostomy

Previous treatment with self-expandable metal stent for same condition

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:	Recruitment stopped
Start date (anticipated):	23-02-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO	
Date:	26-08-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL31101.078.09