Efficacy of a new Wallflex Duodenal Soft stent for palliation of gastric outlet obstruction

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24271

Source
NTR

Brief title
TBA

Health condition

Malignant gastric outlet obstruction

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Boston Scientific

Intervention

Outcome measures

Primary outcome

To assess the efficacy of the WallFlex Duodenal Soft Stent in palliation of GOO-symptoms

Secondary outcome

Safety and overall functional outcomes, including WHO-performance score, days of admission both after stent placement and for (S)AE, quality of life and overall survival

Study description

Background summary

Rationale: Malignant gastric outlet obstruction (GOO) is a late complication of advanced gastric and periampullary malignancies. Self-expandable metallic stent (SEMS) insertion is recommended for palliation of GOO-symptoms in patients with a life-expectancy of less than 2 months. Recently, Boston Scientific released a new duodenal SEMS which has a higher flexibility than previously released SEMS. It is believed that this higher flexibility provides a potential benefit in case of severe strictures or anatomic difficulties. Until now, no data are available on the efficacy of this new SEMS design.

Objective: To evaluate the efficacy of the new WallFlex Duodenal Soft Stent in palliation of GOO-symptoms.

Study design: Prospective, single-center, observational cohort study

Study population: Patients who will undergo treatment of GOO-symptoms in the Erasmus University Medical Center.

Intervention: The WallFlex Duodenal Soft Stent will be used, manufactured by Boston Scientific (Marlborough, USA).

Main study parameters/endpoints: Primary objective of this study will be to assess the efficacy of the WallFlex Duodenal Soft Stent in palliation of gastric outlet symptoms. This will be assessed using the clinical success rate at 2 weeks. Clinical success will be defined as an improvement of the Gastric Outlet Obstruction Scoring System (GOOSS) score to ≥2 (i.e. able to consume soft solids).

Study objective

It is believed that the higher flexibility of the Wallflex Duodenal Soft stent provides a potential benefit in case of severe strictures or anatomic difficulties.

Study design

MEC approval has been granted

Contacts

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Eligibility criteria

Inclusion criteria

• Histologically proven malignant gastric outlet obstruction
• Gastric Outlet Obstruction Scoring System (GOOSS) score of ≤2
• No curative treatment options available
• Planned to undergo duodenal SEMS insertion
• Life expectancy of less than 3 months
• Age ≥ 18 years
• Written informed consent*
*To collect data from the electronic patient system

Exclusion criteria

• Previous SEMS insertion for the same condition
• Patients with pre-procedural evidence of an additional more distally located stricture (i.e. small bowel or colon)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-05-2019
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	24-06-2019
Application type:	First submission

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
NTR-new	NL7822
Other	METC Erasmus MC : MEC-2019-0251

Study results