

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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24271

Bron

NTR

Verkorte titel

TBA

Aandoening

Malignant gastric outlet obstruction

Ondersteuning

Primaire sponsor: Erasmus MC

Overige ondersteuning: Boston Scientific

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

MEC approval has been granted

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	28-05-2019
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	24-06-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7822
Ander register	METC Erasmus MC : MEC-2019-0251

Resultaten