EsophageAl mulTisegmented fully covERed self-expandable metal Stent for malignant strictures: a Safety and Feasibility study

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The main objective of this study is to evaluate the safety, including stent migration rates, and efficacy of placement of the esophageal multisegmented fully covered SEMS with the OTW method in patients with non-operable malignant obstruction of the...

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

Summary

ID

NL-OMON55233

Source
ToetsingOnline

Brief title
EATERS-study

Condition

- Gastrointestinal stenosis and obstruction

Synonym
Esophageal cancer, malignant dysphagia

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Micro-Tech

Intervention

Keyword: Esophagus, Malignant, Stent, Stricture

Outcome measures

Primary outcome

- Safety: Short term (within 7 days after treatment) and long term (after 7 days) major complications and minor complications. Major complications are defined as life threatening and severe complications such as perforation, haemorrhage, fistula formation and severe pain. Minor complications are defined as non-life threatening or moderately severe pain, gastroesophageal reflux and stent migration. Because of the new stent design that should decrease stent migration, we will specifically pay attention to stent migration rates.

- Efficacy: Consisting of

• Clinical outcome, measured at baseline and during follow-up until death with the Ogilvie dysphagia score;

• Technical successful placement of the esophageal multisegmented fully covered SEMS including correct positioning at the stenosis. Technical success is defined as ease of deployment and placement of the stent at the required location.

Secondary outcome

- Recurrent dysphagia: cause of dysphagia will be registered during follow-up;

- Functional outcome after stent placement: expressed as WHO performance, measured at baseline and during follow-up until death;

- Pain related to esophageal stent during follow-up: the first two weeks pain

will be measured daily with a patient diary, using the Visual Analogue Scale

(VAS). After this, every 4 weeks until death the patient will be contacted with

a telephone interview;

Study description

Background summary

The majority of esophageal cancer patients have unresectable disease at presentation. Even after curative therapy, about 20% of patients develop dysphagia from recurrent strictures. Dysphagia is the predominant symptom in 70% of esophageal cancer. Complications include high risk of aspiration and reduced patency of the orogastric pathway, which lead to a profound reduction in quality of life. Therefore palliative therapy has been, and will continue to remain, an important part of the management of esophageal malignancy. The primary goal of palliative treatment in patients with esophageal cancer is to achieve adequate improvement of dysphagia and therefore quality of life, with a reduced need for additional interventions.
Although optimal intervention for treatment of dysphagia has yet to be established, placement of a partially or fully covered self-expandable metal stents (SEMS) is the palliative modality of choice and recommended by the European Society of Gastrointestinal Endoscopy2. This because of their ability to provide instant, long-lasting relief from dysphagia with minimal morbidity and negligible mortality3.

1st generation SEMS: Uncovered SEMS
The first commercially produced self-expandable metal stent was the Wallstent, made of stainless steel. Ultraflex stent, developed by Boston Scientific (Natick, MA, USA) was the first stent to be made of nitinol, a shape-retaining nickel and titanium alloy. Since then, nitinol is most popular stent wire material.

2nd generation SEMS: Covered SEMS
To prevent tumor ingrowth into stent, fully or partially covered stent is introduced in 1990. Covered material is various: Polyurethane, silicone and PTFE.

3rd generation SEMS: Retrievable SEMS
A retrievable fully covered SEMS is introduced in 1997. Drawstrings were attached to stent to help remove or reposition the stent.

4th generation: Self-Expandable Plastic Stent

Polyflex is the first self-expanding plastic stent (SEPS) characterized by removability.

Known complications of esophageal stent placement are esophageal perforation, chest pain, bleeding, fistula formation, gastroesophageal reflux and recurrent dysphagia due to among others tumor/hyperplastic tissue in- or overgrowth, stent migration or food occlusion. Stent migration rates of 6-17% have been described4. Migration rates seem to be higher when using fully covered stent designs, possibly due to reduced adhesion and fixation to the esophageal wall.

The esophageal multisegmented fully covered SEMS is made of nitinol wire and has a silicone cover. It shares similar characteristics with other 2nd and 3rd generation stents which have been used over more than 20 years. Placement is done according to the over-the-wire (OTW) method using fluoroscopic images to control the position, which is considered to be a safe method and is widely used in daily clinical practice5-6. Its multisegmented design is a new aspect and expected to decrease migration rates. The multisegmented fully covered SEMS has been evaluated for palliation of malignant dysphagia and has been approved with a Conformité Européenne (CE) certificate for the maintenance of esophageal lumen patency in malignant dysphagia.

Since there is limited data on the effectiveness in the clinical context, the aim of this study is to evaluate the safety and efficacy of the esophageal multisegmented fully covered SEMS. We will pay specific attention to migration rates during assessment of the safety of the stent.

Study objective

The main objective of this study is to evaluate the safety, including stent migration rates, and efficacy of placement of the esophageal multisegmented fully covered SEMS with the OTW method in patients with non-operable malignant obstruction of the esophagus or esophagogastric junction, extrinsic malignant compression, or recurrent malignant dysphagia after esophagectomy.

Other (secondary) objectives are to assess the effect of the stent on the presence of hyperplastic reaction after implantation, the functional complications and survival.

Study design

A non-randomized prospective clinical study in a single centre (Radboudumc), to evaluate the safety and efficacy of the esophageal multisegmented fully covered SEMS in patients with non-operable malignant obstruction of the esophagus or esophagogastric junction, extrinsic malignant compression, or recurrent malignant dysphagia after esophagectomy.

After stent placement patients will be evaluated with a telephone interview 14 days later and at 4-week intervals until death/stent removal , or until a maximum of 6 months follow-up.

Intervention

Placement of esophageal multisegmented fully covered SEMS

Study burden and risks

Participation in the study does not cause any additional charge to patients. The stent implantation and follow-up are not different from the usual in standard clinical practice. As the stent is designed to prevent migration, this could be a possible advantage of participation in the study. However, a decrease of migration rates has to be confirmed first.

The risk classification is determined as negligible based on the guideline of the *Nederlandse Federatie van Universitair Medische Centra*. The risks associated with the participation in the study are similar to the risks of treatment with any esophageal stent, and do not different from the complications arising from the use of other expandable stent; migration, bleeding, perforation and development of hyperplasia/granulation tissue.

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

- Patients presenting with dysphagia due to a non-operable malignant obstruction of the esophagus or esophagogastric junction including extrinsic malignant compression and recurrence in post-esophagectomy patients;
- Requiring treatment for dysphagia (Ogilvie score of 2-4);
- Life expectancy of less than 12 months;
- Written informed consent;
- Age >= 18 years.

Exclusion criteria

- Stenosis after laryngectomy;
- Distance between the upper edge of the stent less than 2 cm from the upper esophageal sphincter;
- Tumor length of more than 14 cm;
- Esophageal fistula;
- Previous stent placement for the same condition;
- Inappropriate cultural level and understanding of the study;
- Coagulopathy;
- Patients with eosinophilic esophagitis or a esohpageal motility disorder.

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-03-2021
Enrollment:	18
Type:	Actual

Medical products/devices used

Generic name:	Esophageal multisegmented fully covered self-expandable metal stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-05-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-02-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-06-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
ClinicalTrials.gov	NCT04415463
CCMO	NL73180.091.20

Study results

Date completed: 20-07-2022

Actual enrolment: 20

Summary results
Trial is onging in other countries