Esophageal HILZO Covered self-expandable metal stent for palliation of malignant dysphagia: A Safety and Feasibility Study

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The main objective of this study is to evaluate the safety and efficacy of placement of the esophageal HILZO Covered stent with the TTS method in patients with non-operable malignant obstruction of the esophagus or esophagogastric junction,…

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

Summary

ID

NL-OMON45573

Source
ToetsingOnline

Brief title
HILZO-study

Condition

- Gastrointestinal stenosis and obstruction

Synonym
esophageal cancer, esophageal carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: KEBOMED,KEBOMED (distributeur medical device)

Intervention

Keyword: dysphagia, esophagus, malignant, stent

Outcome measures

Primary outcome

The evaluation of all study participants will be registered by the principal

investigator.

The primary objective will be the safety and efficacy of esophageal HILZO

Covered stent.

1. Safety: complications during the follow-up period until death will be

registered and evaluated (migration, food impaction, bleeding, esophageal

perforation, etc.).

2. Efficacy: technical successful TTS placement of the esophageal HILZO Covered

stent, correct positioning at the stenosis under endoscopic guidance.

Secondary outcome

1. Long-term efficacy (dysphagia) will be measured at baseline and during

follow-up until death with the Ogilvie dysphagia score.

2. Pain during follow-up: the first two weeks pain will be measured daily with

a patient diary, using the Visual Analogue Scale (VAS). After this, pain will

be assessed with the VAS during follow-up.

3. The presence of hyperplastic reaction will be objectified if appropriate

during endoscopic controls according to standard care.

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 in this 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, self-expandable metal stents (SEMS) have been largely superseded by other interventions since their introduction in the early 1990s. Esophageal stents have continued to evolve and are now the palliative modality of choice due to their ability to provide instant, long-lasting relief from dysphagia with minimal morbidity and negligible mortality.1

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-explandable Plastic Stent
Polyflex is the first Self-expanding plastic stents (SEPS) characterized removability.
HILZO Esophageal covered stent system belongs to 2nd and 3rd generation stents which have been used more than 20 years and share the similar characteristics with other 2nd and 3rd generation stents

The HILZO Esophageal covered stent 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 TTS placement of HILZO Esophageal covered stent.

In this study we not only investigate the safety and feasibility of the stent alone but also the method of implantation. Due to a new technique of placing the stent with a through-the-scope (TTS) method, the HILZO Esophageal covered stent has several advantages:
o Less invasive procedure for implanting the stent, i.e. no guide-wire insertion required for placement, so the procedure is less demanding on the patient.
o No fluoroscopy is required to ensure correct stent placement
o Higher cost-effectiveness due to reduction of costs of stent placement, due to less material (guide-wire), no special endoscopic and radiologic staff and equipment is required in this procedure.

In the future, when the TTS placement is found to be a safe and feasible method in clinical practice, we will design a subsequent study that compared the TTS stent placement with guide-wire placement to investigate the effect on patient satisfaction and cost-effectiveness.

Study objective

The main objective of this study is to evaluate the safety and efficacy of placement of the esophageal HILZO Covered stent with the TTS 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) objects 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 center (Radboudumc), to evaluate the safety and efficacy of endoscopic TTS placement of the esopageal HILZO Covered stent 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.

Intervention

The HILZO* Esophageal Stent system (BCM Co. Ltd.) is intended for maintaining esophageal luminal patency in esophageal stricture. It is comprised of two components; an implantable metallic stent and a flexible introducer system. After the operation, the stent remains at the intended location, within the patient while the introducer system is removed.

Delivery system: through-the-scope (TTS)
Delivery system is for delivery and release the stent to intended site. The stent is mounted on an inner catheter and is constrained by an outer tube. The outer tube is pulled back by immobilizing the metal tube holder in one hand, grasping the handle with the other hand, and gently sliding the handle along the metal tube (2nd inner catheter) towards the metal tube holder. Retraction of the outer sheath releases the stent. HILZO Stent system has two different delivery systems by its approach. TTS delivery system is 180cm.

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.

The main advantage of TTS stent placement is that it is less complicated and invasive, i.e. no guide-wire placement is required. Moreover, another advantage is that no fluoroscopy is required to verify correct stent placement. The absence of required fluoroscopy in this procedure on the endoscopy department will reduce the costs of stent placement in malignant dysphagia, i.e. no special endoscopic and radiologic staff and equipment is required in this procedure.

In the future, when the TTS placement is found to be a safe and feasible method in clinical practice, we will design a subsequent study that compared the TTS stent placement with guide-wire placement to investigate the effect on patient satisfaction and cost-effectiveness.

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 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

• Non-operable malignant obstruction of the esophagus or esophagogastric junction, extrinsic malignant compression, or recurrent malignant dysphagia after esophagectomy. A tumor is considered inoperable if the patient has local tumor infiltration in the surrounding organs, distant metastases or a poor general health due to serious concomitant disease.
OR
• Recurrent dysphagia after prior radiation with curative or palliative intent for esophageal or gastric cardia cancer.
• Requiring treatment for dysphagia (dysphagia score of 2-4, according to Ogilvie2)
• Written informed consent
• Age >= 18 years

Exclusion criteria

• Inappropriate cultural level and understanding of the study.
• Simultaneous participation in another clinical study
• Life expectancy of less than 12 months
• Stenosis after laryngectomy, or if the distance between the upper edge of the stent is less than 2 cm from the upper esophageal sphincter
• Tumor length of more than 12cm
• Coagulopathy
• Previous stent placement for the same condition

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):	29-03-2017
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Esophageal HILZO Covered self-expandable metal stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	28-02-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-05-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-12-2017
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
CCMO	NL59951.091.16