Evaluatie van stent plaatsing bij patiënten met voedselpassageklachten ten gevolge van een kwaadaardige slokdarmvernauwing.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26240

Source
Nationaal Trial Register

Health condition

Esophageal cancer, Dysphagia, Palliation, Migration, Stent

Sponsors and support

Primary sponsor: University Medical Center Utrecht (UMCU), Departement of Gastronenterology and Hepatology
Source(s) of monetary or material Support: University Medical Center Utrecht (UMCU)

Intervention

Outcome measures

Primary outcome

Migration rate after stent placement; defined as the number of patients presenting with recurrence of dysphagia or other complaints due to stent migration, observed during upper endoscopy.

Secondary outcome

1. Functional outcome: dysphagia and WHO performance score;

2. Short term treatment and long term 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 and gastroesophageal reflux;

3. Reurrent dysphagia; defined as occurrence of tissue ingrowth or overgrowth due to malignant or nonmalignant tissue, stent migration, and food bolus obstruction causing dysphagia needing second;

4. Technical success; defined as ease of deployment and placement of the stent at the required location.

Study description

Background summary

Rationale:

Esophageal cancer is the ninth most common malignancy and the sixth on the list of cancer mortality causes. More than 50% of patients present at a stage that is too advanced for curative therapy. Rapid and persistent palliation of dyphagia is the main goal in most of these incurable cases. Endoscopic placement of a SEMS is one of the most evidence-based palliative treatment options. A broad array of expandable stent types is available. New-design fully covered stents and refinements of existing stent designs continue to be developed in an effort to reduce the risk of recurrent dysphagia because of stent migration, tumoral and nontumoral tissue ingrowth or overgrowth, and to a lesser extent food bolus impaction. Recently, a novel version of a standard fully covered self-expandable stent which combines two specific characteristics which might reduce stent migration was developed. These are flared ends and three layers of covered flaps on the body of the stent. The aim of this study is to evaluate the use of this stent for the palliation of malignant dysphagia.

Objective:

The objective of this study is to determine the migration rate, functional outcome, recurrence of dysphagia and complications of stent use for the palliation of malignant dysphagia.

Study design:

Multicenter, prospective non-randomised open label feasibility study.

Study population:

Patients with (1) inoperable malignant obstruction of the esophagus or esophagogastric junction caused by esophageal or cardia carcinoma or extrinsic malignant compression OR (2) recurrent dysphagia after prior radiation with curative or palliative intent for esophageal or gastric cardia cancer. 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 AND (3) requiring treatment for dysphagia (dysphagia score of 2-4, according to Ogilvie).
(Standard) Intervention: The novel stent design will be placed in all patients as part of standard care. No comparator will be used.

Main study parameters/endpoints:

(1) Migration rate; (2) Functional outcome after stent placement; (3) Short term and long term major and minor complications; (4) Recurrence of dysphagia.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Patients will receive standard care; no additional risks are associated with study participation. The burden consists of follow-up telephone calls 14 days after treatment and monthly thereafter until death by the coordinating researcher. Every telephone call will approximately take 5-10.

Study objective

N/A

Study design

1. Baseline characteristics at day of stent placement;

2. 14 days after stent placement and monthly thereafter until death: dysphagia score, WHO score, presence of specific symptoms, use of symptomatic medication (analgetics, antiemetics, PPI’s).

Intervention

Placement of a novel fully covered stent with antimigration falps across a malignant stricture in the esophagus.

Contacts

Public
P.O. Box 85500
D. Walter
Univeristy Medical Center Utrecht
Department of Gastroenterology & Hepatology
Room F02.618
Utrecht 3508 GA
The Netherlands
+31 (0)88 5755290
Scientific
P.O. Box 85500
D. Walter
Univeristy Medical Center Utrecht
Department of Gastroenterology & Hepatology
Room F02.618
Utrecht 3508 GA
The Netherlands
+31 (0)88 5755290

Eligibility criteria

Inclusion criteria

1. Inoperable malignant obstruction of the esophagus or esophagogastric junction caused by esophageal or cardia carcinoma or extrinsic malignant compression. 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;

2. Recurrent dysphagia after prior radiation with curative or palliative intent for esophageal or gastric cardia cancer;

3. Requiring treatment for dysphagia (dysphagia score of 2-4, according to Ogilvie);

4. Written informed consent.

Exclusion criteria

1. Evidence of tumor growth within 2 cm of the upper esophageal sphincter;

2. A tumor covering < 50% of the circumference;

3. Tumour length of more than 12 cm;

4. Previous treatment with a stent for the same condition;

5. WHO performance score of 4 (100% of time in bed);

6. Patients unfit to undergo conscious sedation;

7. Patients with a poor mental condition or mental retardation, unable to understand the nature and possible consequences of the study or unwilling to undergo follow-up assessments.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2011
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-02-2012
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	NL3169
NTR-old	NTR3313
Other	METC UMCU : 11/428
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A