Assessment of the Removability Claim of the Niti-S Esophageal Covered Stent in Patients with Dysphagia Secondary to a Malignant Stricture and Scheduled for Esophageal Resection

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To assess the feasibility and safety of endoscopic removal of the Niti-S Esophageal Covered Stent under general anesthesia prior to surgical excision of esophageal cancerous lesions, following an escalating time since placement of the stent of 2…

Ethical review	Not approved
Status	Will not start
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Interventional

Summary

ID

NL-OMON32395

Source
ToetsingOnline

Brief title
Niti BTS study

Condition

- Gastrointestinal stenosis and obstruction
- Gastrointestinal therapeutic procedures

Synonym
cancer of the esophagus, esophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Medicon, zal de stents gratis ter beschikking stellen

Intervention

Keyword: Esopghageal Covered Stent, Esophageal Resection, Malignant Stricture, Removability

Outcome measures

Primary outcome

Success rate in stent removal at each time interval (ITT population).

Secondary outcome

NA

Study description

Background summary

The Niti-S Esophageal Covered Stent is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and occlusion of concurrent esophageal fistula. In the present study, it will specifically be used for the relief of dysphagia due to malignant esophageal stenosis prior to esophagectomy.

Study objective

To assess the feasibility and safety of endoscopic removal of the Niti-S Esophageal Covered Stent under general anesthesia prior to surgical excision of esophageal cancerous lesions, following an escalating time since placement of the stent of 2 weeks to 4 months.

Study design

Prospective, single site, open-label pilot study

Intervention

Endoscopic placement and removal of the Niti-S Esophageal Covered Stent

Study burden and risks

Eligible patients (n=30) will receive a Niti-S esophageal covered stent during gastroscopy under conscious sedation with midazolam (day 0 of the study). The benefit of stent placement is the immediate restoration of esophageal patency which will enable patients to eat normally and maintain or, hopefully, increase their body-weight in the waiting period for esophagectomy. A nasogastric feeding tube will therefore not be necessary. Potential (temporary) side-effects of stent placement are retrosternal pain, esophageal bleeding and perforation. Patients will be asked by telephone for their dysphagia score at week 1 and 2 after stent placement. One month after placement of the stent patients will visit the outpatient department for assessment of the dysplagia score and measurement of body-weight. A blood sample will be taken for serum albumin analysis at day 0 and day 28. Prior to stent placement, 28 days after stenting and at the day the stent will be removed, patients will be asked to fill out a quality of life questionnaire. A chest X-ray will be obtained shortly after stent placement and shortly before stent removal. The stent will be removed immediately prior the esophagectomy. So, the patient will then already be under general anaesthesia.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX UTRECHT
Nederland
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX UTRECHT
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Above 18 years of age
• Presenting with an esophageal or gastric cardia carcinoma, confirmed by a tumor histology report
• Requiring treatment for severe dysphagia due to stenosis, as confirmed by an endoscopic examination
• Patient is a candidate for esophageal surgery
• Patient is prepared to sign a study-specific Informed Consent

Exclusion criteria

- Device-related exclusion criteria :
• Esophageal strictures of benign etiology
• Active tumor bleeding lesions
• Patients who are contraindicated for endoscopy and/or surgery, or related testing and/or medications
• Esophageal strictures that need to be dilated to pass the endoscope or the stent delivery system
• Patients with esophago-jejunostomy (following gastrectomy)
• Patients with polypoid lesions;- Study-related exclusion criteria:
• Patients presenting with a highly-positioned esophageal tumor lesion (tumor must be at least 5 cm from upper esophageal sphincter, and the proximal end of the stent must be at least 2 cm from cricopharyngeal muscle)
• Patients with significant preexisting pulmonary or cardiac disease
• Patients at risk of respiratory problems (as confirmed by neck region ultrasound), or requiring tracheo-bronchal stenting
• Patients due for radiotherapy prior to surgery (stent to be placed at least 4 weeks after radiotherapy)
• Patients unwilling and/or unable to submit to follow-up assessments
• Patients unable to fill-out questionnaires
• Patients who are not scheduled for surgery within 2 weeks to 4 months from the stent placement procedure
• Concurrent treatment with an investigational device or drug within 4 weeks of stent placement
• Patients with poor mental condition (psychiatric or organ cerebral disease) rendering the subject unable to understand the nature, scope, and possible consequences of the study or

mental retardation or language barrier such that the patient is unable to give informed consent.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	35
Type:	Anticipated

Medical products/devices used

Generic name:	Endoscopic placement and removal of the Niti-S Esophageal Covered Stent.
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	18-03-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL22012.041.08
Other	volgt