A new design metal stent, SX-Ella stent Esophageal HV, for the prevention of recurrent dysphagia due to migration or tissue overgrowth: a prospective follow-up study

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To evaluate recurrent dysphagia, due to tissue overgrowth or migration, of the SX-Ella stent Esophageal HV in patients with dysphagia from inoperable carcinoma of the distal esophagus or cardia.

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

Summary

ID

NL-OMON30726

Source
ToetsingOnline

Brief title
SX-ELLA stent Esophageal HV for the prevention of recurent dysphagia

Condition

- Gastrointestinal stenosis and obstruction

Synonym
Maligne obstruction esophagus, obstructive esophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cancer, Esophagus, Palliation, stent

Outcome measures

Primary outcome

- Primary endpoint is the occurrence of recurrent dysphagia (stent migration,

tissue overgrowth) including the need for re-intervention.

Secondary outcome

- Secondary endpoints are functional outcome (dysphagia score), the occurrence

of complications and survival.

Study description

Background summary

In patients with inoperable esophageal or cardia cancer, restoration of the ability to eat is the only possible therapy. The aim of palliative treatment is to relief dysphagia rapidly with minimal or no hospital stay, to maintain swallowing during life and to avoid serious complications. In the Netherlands, in many patients with inoperable disease, single dose brachytherapy of placement of a self-expanding metal stent are used for the palliation of dysphagia. A drawback of stents is the occurrence of recurrent dysphagia due to stent migration (12-18% of patients), or tissue overgrowth (approximately 35% of patients).

A new stent, the SX-ELLA stent Esophageal HV (Dr. Karel Volence-Ella-CS, Hradec Kralove, Tsjechië), has been developed for the palliation of malignant dysphagia. The SX-ELLA stent Esophageal HV is delivered in a compressed form inside an introducer sheath with a diameter of 20 Fr. The stent is braided of a wire made of nickel-titanium alloy (nitinol), and is braided of one piece of the wire which makes the stent ends non-traumatic, i.e. the stent does not injure the esophageal wall during an actual deployment or reposition if

misplaced. The stent is essentially not different from other stent types, but differs with some types (Ultraflex stent and Famingo Wallstent) in that it is completely covered and has an anti-migration feature

Study objective

To evaluate recurrent dysphagia, due to tissue overgrowth or migration, of the SX-Ella stent Esophageal HV in patients with dysphagia from inoperable carcinoma of the distal esophagus or cardia.

Study design

This is a one-center, prospective follow-up study. In total, 40 consecutive patients will be included who will be treated with a SX-Ella stent Esophageal HV. Follow-up is until 6 months or until death.

Intervention

Endoscopic esophageal stent placement

Study burden and risks

Patients with dysphagia due to an inoperable carcinoma f the esophagus or gastric cardia. The aim of stent placement is to relief dysphagia rapidly. It is to be expected that patients with a SX-ELLA stent Esophageal HV experience more or less the same burden, with similar risk of complications compared to other stents currently used. In addition, it is to be expected that the SX-ELLA stent Esophageal HV will minimize recurrent dysphagia dur to stent migration or tissue overgrowth

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

a.Inoperable malignant obstruction of the esophagus or cardia (a tumor is considered inoperable if the patient has local tumor infiltration in neighboring organs, distant metastases, or a poor general health due to serious concomitant disease).
b.Recurrent dysphagia after prior radiation with curative or palliative intent for esophageal cancer.
c.Signed informed consent.

Exclusion criteria

a.Evidence of tumor within 2 cm of the upper esophageal sphincter.
b.Esophagotracheal or -bronchial fistula or both.
c.Lesions longer than 12 cm.
d.WHO performance score of 4.
e.Lack of fitness for sedation (including known allergies).

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-02-2007
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	SX-ELLA stent Esophageal HV
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-03-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL16206.078.07