A Comparison of Two Expandable Metal Stents for the Palliation of Malignant Esophageal Disease

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To compare the conventional Ultraflex® Stent with the newly designed Evolution® Controlled Release Stent for the palliation of patients with malignant esophageal disease.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON33264

Source
ToetsingOnline

Brief title
STEMA study

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
malignant esophageal stenosis / esophageal narrowing and malignant esophageal fistulas

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: Dysphagia, Esophageal, Fistula, Malignancy, Stent

Outcome measures

Primary outcome

• To compare the reintervention rate

Secondary outcome

• To compare the procedural failure rate.

• To compare the early functional failure rate.

• To compare the procedure related complications.

• To compare the recurrence rate of dysphagia / esophageal leakage

• To compare the survival rate.

Study description

Background summary

Over the past 20 years, a wide variety of expandable esophageal endoprostheses have been developed to improve placement and reduce stentdysfunction. At present, the Ultraflex® stent (Boston Scientific, USA) is the most frequently used stent. The Ultraflex stent has a polyurethane covered flexible knitted-loop design. The stent has a proximal flange and both proximal and distal a non-covered segment to reduce the risk of migration. The Ultraflex stent is not designed to be repositioned or removed once deployed, although endoscopic removal is often feasible.
The recently designed Evolution Controlled Release Stent (Wilson-Cook Medical, USA) has a silicone sandwich covering. The stent has two uncovered flanges at the proximal and distal end to anchor the stent and reduce the risk of migration. The Evolution stent has a novel delivery system that makes the stent recapturable to allow for repositioning during deployment. The *lasso* loop on the proximal end enables stent removal and repositioning after deployment.

In this prospective randomized study, we will compare the conventional Ultraflex stent with the newly designed Evolution stent for the palliation of

patients with malignant esophageal disease.

Study objective

To compare the conventional Ultraflex® Stent with the newly designed Evolution® Controlled Release Stent for the palliation of patients with malignant esophageal disease.

Study design

Patients, 18 years of age and older, referred for palliative stent placement for malignant esophageal disease are eligible for this study after written informed consent.

Intervention

• Insertion of the Ultraflex® Stent (group 1) or the Evolution® Controlled Release Stent (group 2)

Study burden and risks

None. Stent therapy is a standard therapy for this population.

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, 18 years of age and older, referred for stent placement for malignant esophageal disease

Exclusion criteria

Location of lesions at less than 4 cm from upper gastro-intestinal sphincter.
Lesions longer than 9 cm. Patients who are unable to undergo endoscopy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-06-2009
Enrollment:	80

Type:	Actual

Ethics review

Approved WMO Date:	22-06-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-12-2009
Application type:	Amendment
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	NL27137.078.09