Wallflex stent versus Egis stent for palliation of malignant dysphagia

Published: 19-11-2013
Last updated: 22-04-2024

The goal of this study is to compare the efficacy and safety of the Wallflex stent to the Egis stent.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON40496

Source
ToetsingOnline

Brief title
WAVE-trial

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
cancerous passage disorder, malignant dysphagia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: S&G Biotech

Intervention

Keyword: Dysphagia, Endoscopy, Malignancy, Stent

Outcome measures

Primary outcome

Composite clinical end point of recurrent dysphagia and major complications due to stent placement:

- Recurrent dysphagia is defined as a dysphagia score of >= 2 (according to Ogilvie16) as a result of stent dysfunction after initial improvement of dysphagia to < 2. Stent dysfunction is defined as stent migration, tumor in- or overgrowth or food bolus impaction objectified during upper endoscopy.
- Major complications due to stent placement are defined as complications leading to hospitalization, unintended prolongation of hospitalization, death or repeat endoscopic intervention with a possible or definite association with stent placement as determined by the treating physician.

Secondary outcome

-Technical success; defined as an easy deployment and placement of the stent at the required location, verified by fluoroscopy and/or endoscopy.

-Pain score during the first 14-days after stent placement; scored by the patient on a visual analogue scale (VAS).

-Unrelated major complications

-Minor complications

-Quality of life (EQ5D)

Study description

Background summary

Dysphagia is a frequently encountered problem in patients with a malignancy of or around the esophagus. At presentation, surgery is not possible in >50% of patients. Palliative therapy is the only option then. The main goal of palliative treatment is to provide rapid and persistent relief of dysphagia. For this, endoscopic placement of a self-expandable metal stent (SEMS) is one of the most evidence-based treatment options. Although a large selection of SEMS is currently available, recurrent dysphagia due to stent migration, tumor in- or overgrowth or food bolus impaction remains a problem. The fully covered (FC) Egis stent has been developed to reduce the incidence of recurrent dysphagia as well as the complication rate. We hypothesize that the Egis stent, which is more flexible than the Wallflex stent and has a double stepped shoulder design, leads to less complications and less often to recurrent dysphagia compared to the often used FC Wallflex stent.

Study objective

The goal of this study is to compare the efficacy and safety of the Wallflex stent to the Egis stent.

Study design

multicenter, randomized controlled trial in four Dutch hospitals. Patients will be randomized to receive a FC Wallflex stent or FC Egis stent. FU is done by telephone after 2 weeks, 4 weeks and then monthly for up to 6 months after the procedure, death or stent removal

Intervention

FC Wallflex stent or FC Egis stent

Study burden and risks

-Technical success; defined as ease of deployment and placement of the stent at the required location and verified by fluoroscopy and/or endoscopy.
-Pain score during the first 14-days after stent placement; scored by the patient on a visual analogue scale (VAS).
-Major complications not related to stent placement; defined as complications leading to hospitalization, unintended prolongation of hospitalization, death or repeat endoscopic intervention without a possible or definite association with stent placement as determined by the treating physician.
-Minor complications due to stent placement; defined as minor complications with a possible or definite association with stent placement as determined by the treating physician
-Minor complications not related to stent placement; defined minor complications without a possible or definite association with stent placement as determined by the treating physician.

-Quality of life; measured with the EQ5D questionnaire

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Dysphagia due to an inoperable malignant obstruction of the esophagus or gastric cardia. Dysphagia is defined as: dysphagia score of 2-4, according to Ogilvie. Inoperable disease is defined as local tumor infiltration into surrounding organs, distant metastases or a poor general health due to serious concomitant disease
-Written informed consent

Exclusion criteria

-Evidence of tumor growth within 2 cm of the upper esophageal sphincter
-Tumor length > 12 cm
-Previous stent placement for the same condition
-Karnofsky performance scale of <40%
-Patients unfit to undergo conscious sedation
-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 phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-02-2014
Enrollment:	116
Type:	Actual

Medical products/devices used

Generic name:	Egis stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-11-2013
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	24-04-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	16-09-2014
Application type:	Amendment
Review commission:	METC NedMec

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	NL45348.041.13