Wallflex versus Egis stent for palliation of malignant dysphagia’

No registrations found.

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

Summary

ID

NL-OMON28202

Source
Nationaal Trial Register

Brief title
WAVE-study

Health condition

malignant dysphagia

maligne dysfagie

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: S&G Biotech

Intervention

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 Ogilvie) 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 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 as 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.

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 hypothesis is that the Egis stent, which is more flexible (i.e. lower axial force) 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 fully covered Wallflex stent.

Study design

baseline (before stent):

1. patient characteristics

2. Ogilvie score

3. Karnofsky performance score

4. EQ5D questionnaire

2 weeks:

1. VAS score first 14 days after stent placement

2. Ogilvie score

3. EQ5D questionnaire

4. Presence of specific symptoms (pain, regurgitation, or weight loss), complications and use of symptomatic medication (analgetics, anti-emetics, PPI’s)

1 month:

1. VAS score first 14 days after stent placement

2. Ogilvie score

3. EQ5D questionnaire

4. Presence of specific symptoms (pain, regurgitation, or weight loss),

5. Presence of complications

6. Use of symptomatic medication (analgetics, anti-emetics, PPI’s)

2 months:

1. VAS score first 14 days after stent placement

2. Ogilvie score

3. EQ5D questionnaire

4. Presence of specific symptoms (pain, regurgitation, or weight loss),

5. Presence of complications

6. Use of symptomatic medication (analgetics, anti-emetics, PPI’s)

3 months:

1. VAS score first 14 days after stent placement

2. Ogilvie score

3. EQ5D questionnaire

4. Presence of specific symptoms (pain, regurgitation, or weight loss),

5. Presence of complications

6. Use of symptomatic medication (analgetics, anti-emetics, PPI’s)

4 months:

1. VAS score first 14 days after stent placement

2. Ogilvie score

3. EQ5D questionnaire

4. Presence of specific symptoms (pain, regurgitation, or weight loss),

5. Presence of complications

6. Use of symptomatic medication (analgetics, anti-emetics, PPI’s)

5 months:

1. VAS score first 14 days after stent placement

2. Ogilvie score

3. EQ5D questionnaire

4. Presence of specific symptoms (pain, regurgitation, or weight loss),

5. Presence of complications

6. Use of symptomatic medication (analgetics, anti-emetics, PPI’s)

6 months:

1. VAS score first 14 days after stent placement

2. Ogilvie score

3. EQ5D questionnaire

4. Presence of specific symptoms (pain, regurgitation, or weight loss),

5. Presence of complications

6. Use of symptomatic medication (analgetics, anti-emetics, PPI’s)

Intervention

Patients with malignant dysphagia due to an inoperable malignant obstruction of the esophagus or gastric cardia will be randomly assigned to be treated with a FC Wallflex stent (Boston Scientific, Natick, MA, USA) or FC Egis stent (S&G Biotech Inc., Seoul, Korea) and followed-up for a period of six months or until death.

Contacts

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Eligibility criteria

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-12-2013
Enrollment:	116
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-12-2013
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	NL4154
NTR-old	NTR4307
Other	Ethical committee Utrecht : 13-455
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A