A feasibility study of biodegradable STEnt placement with concurrent single-dose BRAchytherapy for the palliation of dysphagia from esophageal cancer: STEBRA-study.

No registrations found.

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

Summary

ID

NL-OMON27601

Source
Nationaal Trial Register

Brief title
STEBRA-study

Health condition

Patients with onerapbel esophageal carcinoma and dysphagia due to malignant stricture

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

1. Safety: Major and minor complications (short and long term);

2. Clinical outcome: Dysphagia free period;

3. Technical succes.

Secondary outcome

N/A

Study description

Background summary

Rationale: Esophageal cancer is the eighth most common malignancy and the sixth on the list of cancer mortality causes worldwide. More than 50% of patients with esophageal cancer already have inoperable disease at presentation. Most of these patients need palliative treatment to relieve progressive dysphagia. Currently single dose brachytherapy (12 Gy) is the treatment of choice in case of a life expectancy of more than three months. Endoscopic placement of a covered self expandable metal stent is reserved for patients with a relatively poor prognosis or with persistent tumour growth after brachytherapy. Brachytherapy results in a better relief of dysphagia at longer follow up (more than three months) whereas stent placement shows a better relief of dysphagia on short notice (less than three months). Brachytherapy also shows considerable rates of persistent dysphagia due to persistent, slowly regressing or recurrent tumour during the first three months. Therefore, the most optimal treatment could consist of a combination of both treatment modalities; stent placement for the best instant relief of dysphagia and brachytherapy for the best relief of dysphagia at longer follow-up. Recently, biodegradable stents have been introduced. These devices combined with brachytherapy could have several advantages in the treatment of malignant dysphagia compared with brachytherapy alone. Since the stent is biodegradable, it only remains in the esophagus for 3 months, which is long enough to induce immediate relief of dysphagia and short enough to prohibit recurrent dysphagia due to stent induced hyperplastic tissue ingrowth which is seen with permanent self-expandable metal stents. While the stent dissolves, the clinical effect of the brachytherapy will appear.

Objective: The aim of this study is to determine the feasibility and safety of placement of a self expandable biodegradable stent with concurrent single-dose brachytherapy in patients with malignant dysphagia.

Study design: A prospective two-center open label pilot study.

Study population: Patients with dysphagia due to inoperable esophageal cancer are eligible for this study.

Intervention: Patients will be given a BD-ELLA stent in combination with single dose brachytherapy (12Gy).

Main study parameters/endpoints: Safety (major and minor complications), technical success rate (successful procedures after 1-2 endoscopy procedures) and functional outcome (improvement of dysphagia of at least one point after 30 days).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: During the first 30 days after intervention, patients will keep a diary on dysphagia score. If the patient is unable to complete a diary data will be collected by proxy assessment. After the first 30 days, the patients will provide these data on a weekly basis. Patients will be followed up by telephone calls 14 days, 1 month, then monthly until six months after inclusion. During these telephone calls data will be collected with respect to clinical outcome, recurrent dysphagia and complications.

Study objective

Our hypothesis is to improve the time of dysphagia-free interval when compared to treatment with brachytherapy alone.

Study design

Follow-up at 1 and 2 weeks, 1, 2, 3, 4, 5 and 6 months.

Intervention

Placement of a BD esophageal stent with concurrent single dose brachytherapy (12Gy).

Contacts

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Eligibility criteria

Inclusion criteria

1. Inoperable cancer of the esophagus or esophagogastric junction due to locally advanced disease, metastatic disease (as defined by TNM classification) or poor medical condition;

2. Prognostic score ¡Ü5* (in order to benefit from brachytherapy effect);

3. Requiring treatment for dysphagia (dysphagia score of 2-4, according to Ogilvie(36) appendix 1);

4. Written informed consent.

Exclusion criteria

1. Patients with T4, N0-1, M0 in good clinical health, who will be treated with definitive (chemo)radiation;

2. Tumour length of more than 10 cm;

3. Tumour growth within 2 cm of the upper esophageal sphincter'

4. Deep ulceration;

5. Tracheo-esophageal fistula;

6. Macroscopic or microscopic tumour growth into the tracheal lumen;

7. Previous radiation or stent placement;

8. 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:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2009
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-03-2010
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	NL2120
NTR-old	NTR2237
Other	METC UMC Utrecht / CCMO : 09-267 / NL27974.041.09 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A