Safety and efficacy of a biodegradable stent during neoadjuvant therapy in patients with advanced esophageal cancer.

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To investigate the safety and efficacy of a biodegradable esophageal stent during neoadjuvant therapy of patients diagnosed with resectable esophageal carcinoma.

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

Summary

ID

NL-OMON36667

Source
ToetsingOnline

Brief title
EsNeBio.

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
esophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biodegradable, Cancer, Esophageal, Stent

Outcome measures

Primary outcome

Primary outcome measure is safety.

Secondary outcome

Secondary outcome measures are clinical succes, technical success, persistent

or recurrent dysphagia, complications and weight changes.

Study description

Background summary

Most of the patients with locally advanced esophageal cancer require chemoradiotherapy therapy prior to curative resection. This neoadjuvant therapy however often causes acute inflammation and oedema of the esophageal mucosa, which will increase difficulties in swallowing and consequently further impair dysphagia and the nutritional status of the patients. First data on a self-expanding plastic stent (fully covered) showed promising results with regard to improvement of dysphagia and safety during neoadjuvant therapy. There were two main drawbacks; these stent tended to migrate and they had to be removed prior to surgery. We hypothesized that an uncovered biodegradable stent might refute these problems while the improvement of dysphagia remains.

Study objective

To investigate the safety and efficacy of a biodegradable esophageal stent during neoadjuvant therapy of patients diagnosed with resectable esophageal carcinoma.

Study design

Prospective, multi center, clinical study.

Intervention

Endoscopic placement of a biodegradable esophageal stent.

Study burden and risks

Patients will have to keep a dysphagia diary daily for the duration of the study. Moreover they will be seen for follow-up and control by a research fellow on a weekly basis in the outpatient clinic during the 5 week period of radiotherapy. Thereafter patients will be contacted weekly by a research nurse during the remaining period of follow-up. The major risks associated with participation are perforation, haemorrhage and severe retrosternal pain. The benefits will be a quick relief of dysphagia. No extra visits to the hospital are foreseen.

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

* cT1-3 N0-1 M0 esophageal carcinoma.
* Scheduled for neoadjuvant chemoradiation therapy prior to esophagectomy.
* Dysphagia for solid, semisolid or liquid food (dysphagia score 2, 3, 4).
* Age older then 18 years.
* Informed consent.

Exclusion criteria

* Tumor length of more than 10 cm.
* Tumor growth within 5 cm of the upper esophageal sphincter.
* Tumor extension into the stomach more than 5 cm.
* 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

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-10-2011
Enrollment:	16
Type:	Actual

Medical products/devices used

Generic name:	Biodegradable stent

Registration:	Yes - CE outside intended use

Ethics review

Not available

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	NL34625.018.10