External beam radiation therapy versus stent insertion for dysphagia relief in esophageal cancer: a multi-center randomized trial

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Primary objectiveThe primary objective of this study is to compare the efficacy of EBRT versus SEMS insertion for palliation of malignant dysphagia in esophageal cancer patients at 4 weeks after start of treatment.Secondary objectivesSecondary…

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

Summary

ID

NL-OMON48565

Source
ToetsingOnline

Brief title
EXTENT trial

Condition

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

Synonym
difficulty swallowing due to esophageal cancer, Dysphagia due to esophageal cancer

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 neoplasms, External beam radiation therapy, Self expandable metallic stents

Outcome measures

Primary outcome

Primary outcome of this study will be *dysphagia response*, regarded as *1

grade reduction of the Dysphagia Scoring Scale (DSS). Assessment of primary

outcome will be conducted at 4-weeks follow-up.

Secondary outcome

Secondary study endpoints include:

- Dysphagia response over time

- Pain intensity

- Major and minor complication rate

- Quality of Life

- Costs

- Dysphagia free survival and overall survival

Study description

Background summary

The incidence of esophageal carcinoma is rapidly increasing, affecting 455,800 patients worldwide in 2012. At time of diagnosis more than half of patients have incurable disease due to metastases or poor medical condition. Dysphagia is the most common symptom of incurable obstructive esophageal cancer.

Palliative treatment aims to relieve dysphagia, maintain nutritional intake and improve quality of life. As it has been demonstrated that brachytherapy has a superior effect over stent insertion for long-term dysphagia relief, current clinical guidelines advice to use brachytherapy over self-expandable metallic stent (SEMS) insertion for dysphagia relief in patients with a life expectancy greater than 3 months. Nevertheless, previous reports show that the use of brachytherapy in current clinical practice is low and that initial palliative treatment varies with hospital of diagnosis. A recent report on the use of brachytherapy in Italian radiotherapy centers showed that in 7 out of 40 responding centers brachytherapy was used, and only 3 centers considered brachytherapy for initial treatment. This is in accordance to an earlier remark in the ESGE guidelines; the authors stated that the main limitations of brachytherapy include limited availability, technical difficulty, and need for dedicated logistics and expertise.

Alternative treatment with external beam radiation therapy (EBRT) is given for dysphagia relief in esophageal cancer. Both EBRT and SEMS insertion have proved to be effective in palliation of dysphagia symptoms, however, no comparative data about these two different modalities are available. Since we can consider both treatment modalities mainstay in the treatment of malignant dysphagia, comparative data are warranted. Therefore, we propose a study that compares the efficacy of EBRT versus SEMS insertion, for dysphagia relief in patients with esophageal cancer. Results of this study could help to further tailor palliative treatment of patients with esophageal cancer.

Study objective

Primary objective
The primary objective of this study is to compare the efficacy of EBRT versus SEMS insertion for palliation of malignant dysphagia in esophageal cancer patients at 4 weeks after start of treatment.

Secondary objectives
Secondary objectives of this study include:
- To compare DSS-response over time of EBRT versus SEMS insertion
- To compare NRS pain score of EBRT versus SEMS insertion
- To compare major and minor complication rate of EBRT versus SEMS insertion
- To compare quality of life of EBRT versus SEMS insertion
- To compare costs of EBRT versus SEMS insertion
- To compare dysphagia free survival and overall survival of EBRT versus SEMS insertion

Study design

We propose a multi-center randomized trial in the Netherlands. When patients are eligible for inclusion, patients will be randomized to either treatment arm

after informed consent is acquired. The allocation is not blinded to the patient or outcome assessor.

Intervention

Patients will be randomized to either EBRT (5 fractions of 4 Gy each with opposing fields in anterior-posterior direction) or SEMS insertion (partially covered Niti-S S Esophageal Stent).

Study burden and risks

The proposed comparative study will provide data on treatment modalities that we consider mainstay in current clinical practice. Hence, results of this study could provide information to support future studies or guidelines, ultimately, leading to an improvement of the quality of palliative care in patients with esophageal cancer. Considering both treatment modalities are available for standard care, the risk of injury as well as the potential benefits for patients participating in this trial are equal to the risk in patients who are not enrolled. A potential burden of participation could be the demand to complete a diary and several questionnaires. This will not lead to a significant risk of injury.
Blood samples will be obtained at baseline before onset of treatmentPermission for the collection of additional blood samples will be obtained separately. Hence, participants that refuse to undergo additional blood sampling can still participate in the EXTENT trial.

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

Histologically proven esophageal cancer
Patients with metastases or inoperable patients
No curative treatment options available
Dysphagia grade of * 2
Age * 18 years
Written informed consent

Exclusion criteria

Malignant extrinsic compression
Previous stent placement
Evidence of tumor within 2 cm of the upper esophageal sphincter
Presence of an esophagotracheal and/or -bronchial fistula

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-05-2019
Enrollment:	220
Type:	Actual

Medical products/devices used

Generic name:	Self expandable metallic stent (partially covered Niti-S S Esophageal Stent)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-11-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-06-2019
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	NL66604.078.18