External beam radiation therapy versus stent insertion for dysphagia relief in esophageal cancer

No registrations found.

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

Summary

ID

NL-OMON25069

Source
NTR

Brief title
EXTENT trial

Health condition

Esophageal cancer
Dysphagia
Palliative treatment
External beam radiation therapy
Stent insertion

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Erasmus MC

Intervention

Outcome measures

Primary outcome

Primary outcome of this study will be “dysphagia response”, regarded as ≥1 grade reduction of the dysphagia symptom scale. Assessment of primary outcome will be conducted at 4-weeks follow-up.

Secondary outcome

Secondary objectives of this study include comparing: dysphagia response over time, NRS pain score, number of adverse events, quality of life, costs, dysphagia free survival and overall survival.

Study description

Background summary

Update 3 December 2019:
Study has been stopped prematurely for poor accrual

Rationale: 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. 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. Nonetheless, the use of brachytherapy in current clinical practice is low. Alternative treatment with external beam radiation therapy (EBRT) is given for palliation of dysphagia in esophageal cancer. Both EBRT and SEMS insertion have proved to be effective, however, no comparative data about these two different modalities are available.

Objective: The aim of this study is to compare the efficacy of EBRT versus SEMS insertion, for palliation of dysphagia symptoms in patients with esophageal. Secondary objectives of this study include to compare dysphagia response over time, NRS pain score, number of adverse events, quality of life, costs, dysphagia free survival and overall survival.
Study design: Multi-center randomized trial.

Study population: The research population of this study will consist of patients who will undergo palliative treatment for malignant dysphagia due to esophageal cancer.
Intervention: Patients will be randomized to either SEMS insertion (Niti-S S Esophageal Stent) or EBRT (5 fractions of 4 Gy each with opposing fields in anterior-posterior direction).

Main study parameters/endpoints: Primary outcome of this study will be “dysphagia response”, regarded as ≥1 grade reduction of the dysphagia symptom scale. Assessment of primary outcome will be conducted at 4-weeks follow-up.

Study objective

The aim of this study is to compare the efficacy of EBRT versus SEMS insertion for palliation of dysphagia symptoms in patients with esophageal cancer

Study design

Follow-up will be conducted by telephone interviews at 1 week, 2 weeks, 4 weeks, and monthly herafter until a maximum of 6 months or death.

Intervention

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

Contacts

Public
Erasmus Medical Center Rotterdam

M.C.W. Spaander
‘s Gravendijkwal 230

Rotterdam 3015 GC
The Netherlands
+3117040704
Scientific
Erasmus Medical Center Rotterdam

M.C.W. Spaander
‘s Gravendijkwal 230

Rotterdam 3015 GC
The Netherlands
+3117040704

Eligibility criteria

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
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	14-11-2018
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	20-03-2018
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	NL6920
NTR-old	NTR7116
Other	METC ERasmus MC : -

Study results