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

Gepubliceerd: 20-03-2018 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25069

Bron
NTR

Verkorte titel
EXTENT trial

Aandoening

Esophageal cancer
Dysphagia
Palliative treatment
External beam radiation therapy
Stent insertion

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	14-11-2018
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	20-03-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6920
NTR-old	NTR7116
Ander register	METC ERasmus MC : -

Resultaten