Gelijktijdige brachytherapy en biodegradable stentplaating bij inoperbale slokdarmkanker.

Gepubliceerd: 07-10-2009 Laatst bijgewerkt: 18-08-2022

Het is veilig en haalbaar om in 1-2 gastroscopieen zowel een BDstent te plaatsen als brachytherapie toe te dienen.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24619

Bron
NTR

Verkorte titel
STEBRA

Aandoening

Palliatie bij slokdarmcarcinoom
Brachytherapie
Biodegradable stent
Pallation for inoperable esophageal cancer
Brachytherpy
Biodegradable stent

Ondersteuning

Primaire sponsor: UMC Utrecht,
Department of Gastroenterology and Hepatology
Overige ondersteuning: UMC Utrecht,
Department of Gastroenterology and Hepatology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Major and minor complications and technical success rate.

Toelichting onderzoek

Achtergrond van het onderzoek

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:
Major and minor complications, technical success rate and persistent and recurrent dysphagia.

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.

Doel van het onderzoek

Het is veilig en haalbaar om in 1-2 gastroscopieen zowel een BDstent te plaatsen als brachytherapie toe te dienen.

Onderzoeksopzet

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Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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(30) appendix 1);

4. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with T4, N0-1, M0 in good clinical health, who will be treated with radiation and/ or chemotherapy;

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2009
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-10-2009

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	NL1929
NTR-old	NTR2046
Ander register	METC UMCU : 09/267
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A