Palliation of dysphagia due to esophageal carcinoma with irradiation: external vs. internal radiotherapy

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The study hypothesizes that EBRT will result in increased palliation of dysphagia and less re-interventions compared to ILBT during follow-up

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

Samenvatting

ID

NL-OMON26214

Bron
Nationaal Trial Register

Verkorte titel
POLDER1

Aandoening

Esophageal carcinoma; slokdarmkanker; palliation of dysphagia; palliatie passageklachten; external beam radiotherapy; intra-luminal brachytherapy

Ondersteuning

Primaire sponsor: AMC Amsterdam
Overige ondersteuning: AMC Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The improvement of dysphagia score at 3 months (Ogilvie score of ≤ 2) without re-intervention in patients with irresectable esophageal cancer

Toelichting onderzoek

Achtergrond van het onderzoek

This multicenter non-randomized prospective observational cohort study will assess the short-term effect of external beam radiotherapy compared to intra-luminal brachytherapy for palliation of dysphagia in patients with irresectable oesophageal cancer. After treatment, patients are followed up until death and dysphagia scores, quality of life and survival will be documented during one year. Recent patient data on palliative EBRT (5x4 Gy) treatment of esophageal carcinoma will be prospectively collected and compared with a historic ILBT (1x12 Gy) patient cohort (n = 101), originating from the in 2004 published SIREC trial [1].

Since data on EBRT for palliation of dysphagia is scarce, the outcome of the study will provide evidence for the preferred palliative radiation treatment of dysphagia (EBRT or ILBT).

Doel van het onderzoek

The study hypothesizes that EBRT will result in increased palliation of dysphagia and less re-interventions compared to ILBT during follow-up

Onderzoeksopzet

After treatment of dysphagia with EBRT or ILBT patients are followed up weekly up to 8 weeks, and at 3, 6, 9 and 12 months

Onderzoeksproduct en/of interventie

Two treatment arms (101 patients per arm):

1) External beam radiotherapy (5x4 Gy, 4-5 times per week)

2) Intra-luminal brachytherapy (1x12 Gy)

Contactpersonen

Publiek

AMC Amsterdam

Paul Jeene
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-

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Histological proven large cell carcinoma of the esophagus

- M+ disease stage or patients otherwise not a candidate for curative locoregional treatment

- Life expectancy ≥ 3months

- Dysphagia grade ≥2

- Written study-specific informed consent at the time of registration

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Age <18 years

- Pregnancy

- Tumour growth into the tracheal lumen, or suspicion of ingrowth.

- Tumour length of more than 12 cm, including multifocal tumors over a length of more than 12 cm.

- Prior radiotherapy to the esophagus to a radiobiological equivalent dose of >20 Gy. (EQD2 > 20Gy, using α/β = 2).

- (partial) resection of the esophagus.

- Chemotherapy for esophageal cancer <1 week prior, during, or <1 week after radiotherapy.

- Esophageal stent in situ

- Tumoral extension of >5 cm in the cardia of the stomach

- CT-thorax more than 3 months before start of treatment (?)

- Inability to understand the nature and possible consequences of the study or unwilling to undergo follow-up assessments.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2016
Aantal proefpersonen:	202
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	13-07-2018
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	NL7198
NTR-old	NTR7397
Ander register	W16_172#16.203 : AMC

Resultaten

Samenvatting resultaten

1. Homs MY et al. Single-dose brachytherapy versus metal stent placement for the palliation of dysphagia from oesophageal cancer: multicentre randomised trial. Lancet. 2004 Oct 23-29;364(9444):1497-504.