Palliation of Obstructive Local Disease of the Esophagus by Radiotherapy

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The aim of this study is to compare the palliative effect of external beam radiotherapy with the palliative effect of intraluminal brachytherapy in the palliation of patients with obstruction of incurable oesophageal cancer. The outcome of the study…

Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON42160

Source
ToetsingOnline

Brief title
POLDER study

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
esophageal cancer, esophageal carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: KWF subsidie voor datamanagement is aangevraagd

Intervention

Keyword: dysphagia, esophageal neoplasm, palliative care, radiotherapy

Outcome measures

Primary outcome

Improvement of dysphagia on the dysphagia scale according to Mellow en Pinkas ,

without reintervention.

Secondary outcome

Duration of palliation of dysphagia

overall survival

quality of life

complication risk

Study description

Background summary

National guidelines for the preferred treatment of patients with obstructive symptoms of oesophageal cancer differ between countries by the lack of randomised trials. Intraluminal brachytherapy is the advocated treatment according to the Dutch guidelines for patients with a life expectancy of more than 3 months. However external beam radiotherapy is mostly used in daily clinical practice in the Netherlands and is mostly advocated in foreign guidelines.

Study objective

The aim of this study is to compare the palliative effect of external beam radiotherapy with the palliative effect of intraluminal brachytherapy in the palliation of patients with obstruction of incurable oesophageal cancer. The outcome of the study will reveal the best radiation treatment option for patients with obstructive symptoms and will improve treatment uniformity.

Study design

open, randomised study.

Intervention

One group will be treated with external beam radiotherapy in 5 fractions of 4 Gy whereas the other group will be treated with intraluminal brachytherapy in one fraction of 12 Gy.

Study burden and risks

No additional risks compared to the two standard treatment options.
Both treatments can give short term increasement of pain during swallowing.
Strictures, filsula formation, bleeding, ulceration and fever can occur in both treatments.

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

Histological proven large cell carcinoma of the esophagus
M+ disease stage or patients otherwise not a candidate for curative locoregional treatment
Life expectancy * 3 months
Dysphagia grade *2
Written study-specific informed consent at the time of registration

Exclusion criteria

Age <18 years
Pregnancy
Macro- or microscopic 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 oesophagus/mediastinum more than 20 Gy or any prior brachytherapy to the oesophagus.
(partial) resection of the oesophagus
Chemotherapy for esophageal cancer <6 weeks prior to (or during) radiotherapy
Esophageal stent in situ
Tumoral extension of > 4 cm in the cardia of the stomach
CT-thorax more than 3 months before start of treatment
Intraluminal brachytherapy medically or technically not possible
Inability to understand the nature and possible consequences of the study or unwilling to undergo follow-up assessments.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	210
Type:	Anticipated

Ethics review

Approved WMO Date:	02-02-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-03-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-03-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL50774.018.14