A Randomized Trial of Dose Escalation in definitive Chemoradiotherapy for patients with Oesophageal cancer *ART DECO*

Published: 20-02-2012
Last updated: 01-05-2024

To improve the local tumor control rate by escalating the radiation dose in definitive chemoradiotherapy for patients with locally irresectable or medically inoperable carcinoma of the esophagus or gastric junction without distant metastases (stage...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON41614

Source
ToetsingOnline

Brief title
ART DECO

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
esophagus cancer, Oesophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: KWF kankerbestrijding

Intervention

Keyword: Chemoradiation, Dose escalation, Oesophageal cancer

Outcome measures

Primary outcome

local tumor control

Secondary outcome

survival, toxicity

Study description

Background summary

Patients with oesophageal cancer suffer a high chance of local recurrence resulting in short term death. The local recurrence causes severe and frequent complaints without possibilities for palliation. Radiation dose for oesophageal cancer are traditionally low due to side effects as a result from large irradiation fields used in the past. The dose is considerably lower than the radiation dose applied for neighbouring tumors like hypopharyngeal cancer. The treatmentresults are also poorer than with hypopharyngeal cancer. The addition of chemotherapy as sensitizer for the radiation provved efficient as demonstrated in the Dutch CROSS study comparing low dose radiation with and without concomitant chemotherapy. As a successor of the forementioned study the Dutch Oesophageal cancer group and the "landelijk platform Radiotherapie voor Gastro-Enterologische tumoren" propose the undelying study. In this study we use possibilities provided by modern radiation oncology to decreasing the dose to the surrounding tissues. We use tis increase in therapeutic window to increase the dose to the tumor whilst maintaining the dose to the organs at risk to achieve a 15% increase in local control and avoidance of the complaints en death a recurrence brings.

Study objective

To improve the local tumor control rate by escalating the radiation dose in definitive chemoradiotherapy for patients with locally irresectable or medically inoperable carcinoma of the esophagus or gastric junction without

distant metastases (stage T1-4N0-3M0).

Study design

Multicenter, prospective randomized phase III clinical trial.
Arm I: standard dose of 50.4 Gy plus concurrent carboplatin and paclitaxel
Arm II: as arm I plus a concomitant daily boost dose of 0.4 Gy to the primary tumor leading to a total tumordose of 61.6 Gy in 2.2 Gy fractions.

Intervention

Radiation dose escalation to the primary tumor.

Arm I: standard dose of 50.4 Gy plus concurrent carboplatin and paclitaxel
Arm II: as arm I plus a concomitant daily concomitant boost dose of 0.4 Gy to the primary tumor leading to a total tumordose of 61.6 Gy in 2.2 Gy fractions.

Study burden and risks

Patients in the experimental ar have a higher risk for radiation pneumonitis, dysphagia caused by mucositis and ulceration. At long term there is a higher risk for fibrotic stricutres and esophageal perforations.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

T1-4, N0-3, M0 adeno- or squamous cell carcinoma of the esophagus or esophageal gastric junction referred for definitive chemoradiation

Exclusion criteria

tumors > 10 cm, unfit for definitive chemoradiation, pathologic lymphnodes at both truncus coeliacus and supraclavicular level, esophageal stent in situ.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-09-2012
Enrollment:	260

Type:	Actual

Ethics review

Approved WMO Date:	20-02-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-01-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-01-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-06-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	19-11-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-07-2016
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	NL38343.018.11