Repeat CT scans to determine shape variation during radiotherapy of the esophagus in esophageal cancer patients: ReShape study

Published: 22-11-2012
Last updated: 18-07-2024

Primary objective: to investigate the intra- and interfraction motility of the CTV (the primary tumor as well as any affected celiac lymph nodes) in radiotherapy for esophageal cancer, and to determine adequate CTV-ITV margins.Secondary objective:...

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

Summary

ID

NL-OMON36849

Source
ToetsingOnline

Brief title
ReShape

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
esophageal cancer; esophageal malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 4D-CT, esophagus, ITV, shape variation

Outcome measures

Primary outcome

The intra- and inter fraction motility of the CTV (both random and systematic errors) will be used to design a margin recipe: based on the differences a formula will be given for the expansion from CTV to ITV, which will ensure a change for coverage of the target volume of at least 95% on every treatment day.

Secondary outcome

Based on the differences in the motility on the two 4DCT scans, it will be investigated whether one 4DCT scan is sufficient for determination of the intra-fraction motility.

Study description

Background summary

Radiotherapy plays an important role in the treatment of esophageal cancer. The esophagus is a very motile organ due to respiration, heartbeat, peristalsis, dilatation and gastric filling. This motility needs to be incorporated in the radiation plan, so that the clinical target volume (CTV) is adequately covered without underdosage. To accomplish this, the CTV needs to be expanded with adequate margins to an internal target volume (ITV), around which the planning target volume (PTV) is defined. Unfortunately, there is only limited data available on the magnitude of the esophageal motility.

Study objective

Primary objective: to investigate the intra- and interfraction motility of the CTV (the primary tumor as well as any affected celiac lymph nodes) in radiotherapy for esophageal cancer, and to determine adequate CTV-ITV margins.
Secondary objective: to investigate whether one 4DCT scan is sufficient for determination of intra-fraction motility.

Study design

This is an observational study. Of all participating patients who will be treated with long course radiotherapy (*10 fractions, with or without chemotherapy) four additional CT scans and two additional 4DCT scans will be acquired in the first two treatment weeks. The motility will be evaluated by delineation of the CTV onto all CT scans.

Study burden and risks

Participants will undergo 4 additional CT scans en two 4DCT scans immediately prior to or after a treatment fraction in the first two weeks of their treatment. The 4DCT will be made at the same session as the planning CT and one of the additional CT scans and only acquire a few minutes more. The total estimated additional time investment of the patient is 60 minutes (15 minutes per additional CT).
The estimated total extra radiation as a result of the additional scans is 0,18-0,24 Gy, which is 0,3-0,8% of the total treatment dose. The risks of this additional dose is negligible.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 Za
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 Za
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Esophageal cancer
cT1-3, any N
WHO<=< 2

Exclusion criteria

Previous thoracic surgery
Previous thoracic radiotherapy
cT4

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	18-12-2012
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	22-11-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL41642.058.12