Repeat CT for evaluation of inter- and intrafraction changes during curative thoracic radiotherapy; An exploratory pilot study.

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To evaluate the impact of inter-fraction tumour and organ geometrical dislocation for moving tumours on photon and proton radiotherapy treatment plans in order to create robust intensity modulated photon- and/or proton treatment plans.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Thoracic disorders (excl lung and pleura)
Study type	Observational invasive

Summary

ID

NL-OMON43004

Source
ToetsingOnline

Brief title
REACT-study

Condition

- Thoracic disorders (excl lung and pleura)

Synonym
(non) small cell lung cancer stage 3, breast cancer or (non) Hodgkin lymphoma, Patients with esophageal cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Inter- and intrafraction changes, Radiotherapy, Repeat CT, Thoracic

Outcome measures

Primary outcome

Dose coverage of the target volumes (CTVs).

Secondary outcome

• Margin for inter-fraction variation (in relation to the ITV and PTV margin)

• Areas of under dosage

• Areas of over dosage

• DVH parameters of the heart (MHD, V5, V10, V20, V30, V40, V50, V60)

• DVH parameters of the lungs (MLD, V5, V10, V20, V30, V40, V50, V60)

Study description

Background summary

Radiotherapy (combined with chemotherapy) is increasingly applied in the curative treatment of tumours located in the thoracic region, including esophageal cancer, lung cancer, breast cancer, and (non) Hodgkin lymphoma. Accurate treatment planning and dose delivery is essential for radiotherapy to be effective. However, accuracy is challenged by tumour and organ motion both within the fraction (intra-fraction movements) and from fraction to fraction (inter-fraction movements or changes). At present, radiotherapy treatment planning is typically performed on one (3D or 4D) planning-CT scan before start of the treatment. However, inter-fraction set up variations and organ motions (including baseline drift) can lead to differences between the calculated dose distribution on the planning-CT and the radiation dose actually received by the tumour and normal organs (actual given dose) [1]. In photon radiotherapy, assessment of these effects is essential to determine margins from clinical

target volume (CTV) to planning target volume (PTV) in order to irradiate the tumour adequately while minimizing the dose to the organs at risk (OARs).
For proton beam therapy (PBT), knowledge of tumour and organ motion will be even more important [2,3]. The major potential advantages of PBT for tumours in the thoracic region in terms of prevention of radiation-induced side effects are challenged by the respiratory motion of the tumour, breast, esophagus, diaphragm, heart, stomach, and lungs. Setup errors and inter- and intra-fractional organ motion cause geometric displacement of the tumours and normal tissues, which blurs the dose gradients from target volume to normal tissue. Furthermore, it can result in changes in tissue densities in the beam path, which can alter the position of the Bragg peaks, in turn leading to distorted dose distributions. If pencil beam scanning techniques are used to treat moving tumours, there is interplay between the dynamic pencil beam delivery and target motion. This phenomenon can cause additional deterioration of the delivered dose distribution, usually manifesting as significant local under and/or over dosage [4]. It is therefore essential to incorporate motion-related uncertainties during treatment planning [5].
In this study, we want to evaluate the impact of inter-fraction tumour and organ motion on photon and proton radiotherapy treatment planning - while taking into account intra fraction movements - in order to create robust intensity modulated photon- and/or proton treatment plans (IMRT, IMPT).

Study objective

To evaluate the impact of inter-fraction tumour and organ geometrical dislocation for moving tumours on photon and proton radiotherapy treatment plans in order to create robust intensity modulated photon- and/or proton treatment plans.

Study design

Pilot-study

Study burden and risks

During the radiotherapy treatment course, patients will undergo weekly repeat planning CT scans in treatment position without contrast agents in order to evaluate the impact of inter-fraction tumour and organ motion.
The additional radiation dose of these 3-6 extra 4D-CT*s and a maximum of 10 cone-beam CTs (7mSv) is extremely low (3-6 x 25-30mSv) compared to the therapeutic radiation dose (30-60 Gy). The risks are therefore negligible and the burden is low.

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

- Histologically proven esophageal cancer, stage III NSCLC or SCLC, breast cancer, or (non) Hodgkin lymphoma.
- Scheduled for external-beam photon radiotherapy to the thoracic region with curative intention.
- Scheduled for (neo-)adjuvant or primary (chemo)radiotherapy.
- WHO 0-2.
- Age >= 18 years.
- Written informed consent.

Exclusion criteria

- Relative contra-indications, such as pain, for lying on the treatment or CT couch.
- Non compliance with any of the inclusion criteria.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-12-2016
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	23-09-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL57550.042.16
Other	volgt