Optimizing (breathing) techniques for radiotherapy of esophageal and lung carcinomas; a pilot study.

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Primary objective: To determine the optimal breathing technique to minimize the dose to the heart of radiotherapy for esophageal and lung cancer using current photon techniques, without compromising the dose to the lungs. Secondary Objectives: 1. To...

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

Summary

ID

NL-OMON43647

Source
ToetsingOnline

Brief title
ABC-study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Respiratory tract neoplasms

Synonym
Esophageal- and lung carcinomas

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: (chemo) radiotherapy, Active Breathing Controle (ABC), CPAP, Mean Hart Dose (MHD)

Outcome measures

Primary outcome

Dose to the heart (mean heart dose, MHD), dose to the lungs (mean lung dose,

MLD), robustness parameters (homogeneity index; coverage of clinical target

volume).

Secondary outcome

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

• DVH parameters of specific subunits of the heart

• ITV margin (margin for breathing movement defined as ITV - GTV)

• Lung dose (mean lung dose (MLD, V5, V10, V20, V30, V40, V50, V60)

• Position of the heart in relation to the target volumes

• Lung volume

• NTCP pulmonary toxicity

• (NTCP heart toxicity)

Study description

Background summary

Neo-adjuvant chemoradiotherapy (neo-CRT) is increasingly applied in the curative treatment of esophageal cancer, with the aim to downstage the tumor, to increase the rate of radical resections, and consequently to improve the survival rates. Due to improved survival, it will become increasingly important to minimize the radiation-induced toxicity among long-term survivors.
In the management of locally advanced non small cell lung cancer (NSCLC), radiotherapy is the standard treatment modality. However, the dose that can be

safely applied to the tumour is limited by the risk of cardiac and pulmonary complications, which even led to decreased survival in a randomised study, when a higher tumor dose was administered [1].
Radiation induced pulmonary and cardiac toxicity are the most important late side effects after thoracic radiotherapy [2-4].
The aim of this study is to reduce the radiation dose of heart (and lungs) in order to reduce the toxicity risk.

In recent years, the active breathing control (ABC) technique has been introduced in the radiotherapy for left sided breast cancer patients, to minimize the radiation dose to the heart. These patients are irradiated in the inspiration phase, in which the distance between the heart and the breast is largest, while the lungs extend.
Breath hold might also be beneficial for radiotherapy of esophageal and lung tumors. For these patients the expiratory phase might theoretically be more beneficial to reduce the heart dose. However, the inspiration phase might be better for the dose to the lungs, which consequently allows cardiac dose reduction.
In a very recently published study, favorable radiotherapy planning parameters (tumor motion; mean lung dose, mean heart dose) were achieved using continuous positive airway pressure (CPAP) in the treatment of lung tumours [6]. CPAP is routinely used by patients at home during the night for treatment of obstructive sleep apnea. In that study it was shown to be feasible for radiotherapy planning as well as treatment itself. However, CPAP-supported radiotherapy was not compared with any breath-hold techniques in that study

Study objective

Primary objective:
To determine the optimal breathing technique to minimize the dose to the heart of radiotherapy for esophageal and lung cancer using current photon techniques, without compromising the dose to the lungs.

Secondary Objectives:
1. To investigate the differences in dose distribution using the different breathing techniques (CPAP vs. ABC in inspiration, expiration) for 3D-CRT, IMRT and proton radiotherapy.
2. To investigated the effect on the ITV margin (ITV minus GTV) and on the dose distribution to the planning target, heart and lungs.
3. To evaluated the relationship between cardiac and pulmonary dose parameters using different breathing and radiotherapy techniques.

Study design

This is an in silico planning comparative study.

Intervention

Active Breathing Controle

Study burden and risks

Participation in this study does not involve any additional risk to patients, besides the risk incurred by additional CT-scans. Patients will undergo a free breathing 4D planning-CT (including spiral CT) combined with 3 additional CT*s in inspiration breath-hold and in expiration breath-hold and a 4D-CT using CPAP. The additional radiation dose of the 3 extra CT*s is extremely low compared to the radiation dose of the treatment. 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 (adeno-, or squamous cell carcinoma) of the mid or distal esophagus or stage III Non-Small Cell Lung Cancer (NSCLC) (any histological subtype).
• Scheduled for external-beam photon radiotherapy with curative intention.
• WHO 0-2
• Age >= 18 years
• Written informed consent.

Exclusion criteria

• Serious respiratory distress
• Noncompliance with any of the inclusion criteria.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-01-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	21-10-2015
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-03-2016
Application type:	Amendment
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
ClinicalTrials.gov	NCT02497664
CCMO	NL54038.042.15