Prediction of radiation induced lung damage based on dose distribution and tumour location. A pilot study.

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To investigate the newly developed method to study lung density changes using CT-scan, in a small patient population. The relationship between radiation induced lung density changes and dose distribution/tumor location will be investigated.

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON33481

Source
ToetsingOnline

Brief title
RT2009-06

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
Lung cancer (both NSCLC and SCLC)

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Afdeling radiotherapie

Intervention

Keyword: Computed Tomography (CT), Dose distribution, Radiation induced lung damage, Radiotherapy

Outcome measures

Primary outcome

Density changes measured with serial CT-scans scored using the newly developed

quantification method.

Secondary outcome

. The regional dependency of structural lung damage (tumor location)

. The relationship between lung density changes and dose distribution

. The dynamics of structural lung damage (density changes) in time

Study description

Background summary

Radiotherapy is based on reaching the equilibrium between optimal tumor control and an acceptable chance of radiation induced side effects. In the case of lung cancer, the prediction of radiation induced lung damage based on physical dose volume-parameters is limited. Thus, some patients may be undertreated, receiving lower doses than that they may safely tolerate.

This study aims to investigate the relationship between dose-distrbution and tumor location on the development of radiation induced changes in lung density. In the study the newly developed method for quantification of lung density changes using CT-scans will be used. The acquired data will be incorporated in the prediction models. If the prediction of radiation induced lung damage can be improved, a higher dose may be administered to a subset of patients, thus improving local control and survival with an acceptable chance of toxicity.

Study objective

To investigate the newly developed method to study lung density changes using CT-scan, in a small patient population.
The relationship between radiation induced lung density changes and dose

distribution/tumor location will be investigated.

Study design

Observational pilot study.

Study burden and risks

Prior to start of radiotherapy, patients will undergo a routine plannings-CT-scan of the thorax. In case of participation in the study, the planning-CT-scan is extended with one extra series, i.e. the blank deep inspiration CT-scan. During follow-up, the research CT-scans consist of a blank deep inspiration CT-scan of the thorax, 6-26-52 weeks after (chemo)radiotherapy. These CT-scans will be made at the department of radiation oncology. The time-points coincide with regular follow-up visits at the department of radiation oncology. Thus, no extra visits are necessary.

The radiation dose of the 4 CT-scans has been calculated at 40 mSv. This dose is negligible when compared to the radiotherapy dose given (approximately 45.000-60.000 mSv).

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

. Age > 18 years
. WHO PS 0-2
. Stage IIIA/IIIB Non Small Cell Lung Cancer (NSCLC). Planned for conventionally fractionated radiotherapy with or without concomitant chemotherapy, 51-60 Gy.
. Limited disease Small Cell Lung Cancer, i.e. tumor confined to hemithorax without evidence of distant metastases or malignant pleural effusion. Planned for conventionally fractionated (chemo)radiotherapy, 45 Gy.
. Adequate pulmonary function
. Life expectancy of at least 6 months
.. Before patient registration, informed consent must be given

Exclusion criteria

. WHO PS=3
. Life expectancy less than 6 months

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2009

Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO 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	NL29017.042.09