Adaptive Image-Guided Radiotherapy (IGRT) for lung cancer using repeat treatment planning CT scan and PET-CT scans.

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To establish the proportion of patients in whom an initial radiotherapy plan does not provide similar, or improved coverage, on a repeat planning procedure after 15 fractions. To implement adaptive radiotherapy.

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory tract neoplasms
Study type	Interventional

Summary

ID

NL-OMON30265

Source
ToetsingOnline

Brief title
Repeat imaging for treatment planning during radiotherapy in lung cancer

Condition

- Respiratory tract neoplasms

Synonym
cancer of the airways, lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW

Intervention

Keyword: adaptive radiotherapy, imaging, Lung cancer, treatment planning

Outcome measures

Primary outcome

1.To establish the proportion of patients in whom an initial radiotherapy plan

does not provide similar or improved coverage on a repeat planning procedure

after 15 fractions.

2. To indentify the characteristics of this sub-population of patients and

design adaptiveimaging protocols to account for time trends.

3. Establish the magnitude of reduction in toxicity risk to lung and esophagus

in patients for whom reductions in PTV are possible

Secondary outcome

nvt

Study description

Background summary

Conventional radiotherapy for locally-advanced lung cancer is typically delivered using once-daily fractions of between 2-2.6 Gy over a period ranging from 4.5 to 6.5 weeks. The use of 4-dimensional CTscans permit the use of smaller radiation fields to encompass the tumor. A treatment plan is generated and treatment delivery is based on the assumption that the pre-treatment planning target volume (PTV) is representative for the entire course of treatment. However, the tumor volume and/or location can change during a 4-6 week course of radiotherapy due to so called *time trends* .
A repeat of the initial 4DCT (or CT-PET scan) after 3 weeks of treatment* can identify time trends. This facilitates implementation of 'adaptive IGRT*, an approach which has the potential to both improve treatment accuracy and further reduce normal tissue toxicity in locally advanced lung cancer. The proposed

studies are a first step in acquiring this information.

Study objective

To establish the proportion of patients in whom an initial radiotherapy plan does not provide similar, or improved coverage, on a repeat planning procedure after 15 fractions.
To implement adaptive radiotherapy.

Study design

Number of patients: 40 patients, at least 25 of whom will be undergoing concurrent chemo-radiotherapy.
Timing of repeat 4DCT or CT-PET: Directly after the 15th fraction of radiation
Analysis:
1.The repeat 4D imaging study will be co-registered with the initial 4D study
2.The PTV will be rapidly reconstructed on repeat 4DCT
3.Geometric differences between the initial and second PTV will be evaluated
4.The initial treatment plan will be projected upon the new PTV to assess dosimetric coverage.
5.The treating clinician will decide if the plan will have to be modified in accordance with the criteria specified below (intervention)

Intervention

The treating clinician will decide if the plan will have to be modified in accordance with the following criteria. Geometric displacement will always be corrected. Reductions in field sizes for primary lung tumors will only be performed in cases where the risk of radiation pneumonitis is high (i.e. an initial V20 greater than 35%) and with a low risk of having microscopic extension in the distal tumour margins, e.g. based upon endobronchial tumor extent and/or the findings of FDG-PET scans.

Study burden and risks

Patients will undergo a repeat scan immediately after the 15th fraction (3 weeks after starting radiation therapie). Consequently patients will have to stay longer in the hospital for a maximum of one hour.
Patients receive a relatively small extra radiation dose (CTDI 52.7 mGy), which is minor compared to the therapeutic radiation dose received during treatment, typically in the range 5000 to 6600 cGy.

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

Eligible patients who will undergo a 4DCT or 4DCT-PET planning scan, and in whom (i) a pre-treatment GTV can be identified and (ii) will receive a minimum dose of 46 Gy in 4 weeks

Exclusion criteria

Patients who will be irradiated after a complete response to chemotherapy or after a complete surgical resection

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	NL14671.029.06