Comparison of a slowscan ITV, 4DCT ITV/MidV and ABC CT in stage I/II NSCLC patients (IMA study)

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Evaluate the differences in the three CT techniques, concerning differences in target volume, dose differences and feasibility. This study will result in an advice which CT technique should be used in the near future, in order to treat the stage I/...

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

Summary

ID

NL-OMON42058

Source
ToetsingOnline

Brief title
Scanning techniques in stage I/II NSCLC patients

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
Non Small Cell Lung Cancer; Lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Radiotherapiecentrum West
Source(s) of monetary or material Support: nvt

Intervention

Keyword: Active Breathing Control, ITV, MidVentilation, NSCLC

Outcome measures

Primary outcome

Comparison of target volumes (tumour plus normal tissue);

measuring the differences in dose to normal lung tissue;

comparison of the feasibility of scan techniques for this patient group.

Secondary outcome

Duration of the CT technique: will the patient be able to pursue the CT

technique?

Study description

Background summary

Tumours in the lung tend to move as a function of the respiration cycle.
Several CT scanning techniques have been developed to counteract or compensate for tumour movement.
This study compares three diagnostic CTscan techniques. The extra CTscans are used as standard techniques in various institutions in the Netherlands and UK.
Our patients receive the current standard lung cancer treatment regardless of participation in this study.

Study objective

Evaluate the differences in the three CT techniques, concerning differences in target volume, dose differences and feasibility.

This study will result in an advice which CT technique should be used in the near future, in order to treat the stage I/II NSCLC patients with the most optimal radiation technique.

Study design

Potential participants receive information concerning this study. Only after

informed consent they will be included in this study.
In this study 15 patients receive next to standard slow scan two extra CT scans (4DCT & ABC).

Clinical, technical and logistical aspects of the different scan techniques will be compared.

Study burden and risks

95% of the patients receive less than 24 mSv plus 10 mSv (long CT scan) for standard CT diagnostics. The standard therapeutic radiation level is 55000 mSv in the tumour and in the order of 10000 mSv in normal lung tissue.
The extra study scans, two long CT scans are performed the same day in addition to the standard scans. In the worst case scenario this results in 2 * 25 mSv (25 = 10 * 2.5 times average long scan) additional radiation to the lungs, about 5 promile of the therapeutic radiation level. This extra dose remains within the clinical acceptable therapeutic range.
The extra scan time (30 minutes for the study) results in an increase of about 20% overall treatment time. The use of intravenous contrast is not indicated.

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

Patients with NSCLC stage I (T1a,bN0M0 or T2aN0M0) or stage II
Radical radiation treatment
Age * 18 yrs
Written informed consent

Exclusion criteria

Palliative radiation therapy
Not able to perform written informed consent
Patient is pregnant

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-01-2015
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	05-01-2015
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	NL51110.098.14