Quantification of mediastinal lymph node position variability by implanted fiducial markers using Cone Beam CT in Non-Small Cell Lung Cancer patients treated with radical irradiation

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Hypothesis: Fiducial markers implanted in mediastinal lymph nodes by EUS-FNA or EBUS will show inter and intra-fraction lymph node position variability on 4D-(CB) CT-scansObjective: To quantify respiratory induced mediastinal lymph node motion and...

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

Summary

ID

NL-OMON38000

Source
ToetsingOnline

Brief title
Quantification of mediastinal lymph node position variability

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
lung cancer, non-small cell lung carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: NKI- AvL radiotherapie afdeling

Intervention

Keyword: CBCT, Fiducial marker, NSCLC

Outcome measures

Primary outcome

Quantification of inter- and intra-fraction baseline variations and respiratory motion amplitude variations of mediastinal lymph nodes over the course of radiotherapy, in NSCLC patients

Secondary outcome

Define lymph node motion in mm in 3 directions

• Correlate Pulmonary function tests to variability of the lymph node position

• Correlate variability of the lymph node to primary tumor position variability

• Quantify required safety margins of mediastinal radiotherapy to account for variability

Study description

Background summary

Safety margins are required to account for inter- and intra-fraction position variabilities and respiration induced amplitude variability of tumours and pathologic lymph nodes over the course of radiotherapy. While these variabilities have been accurately quantified for the primary tumor using repetitive 4D-CBCT scans over the course of treatment, they are more or less unknown for the mediastinal lymph nodes. This is partly due to the fact that soft-tissue contrast of 4D-CBCT is insufficient to detect the position of the lymph nodes. By implantation of fiducial markers in the mediastinal lymph nodes, an accurate surrogate of lymph node position is created that allows

accurate quantification of inter- and intra-fraction position variabilities and respiration induced amplitude variability

Study objective

Hypothesis: Fiducial markers implanted in mediastinal lymph nodes by EUS-FNA or EBUS will show inter and intra-fraction lymph node position variability on 4D-(CB) CT-scans

Objective: To quantify respiratory induced mediastinal lymph node motion and inter-fraction, intra-fraction baseline variation in radiated lung cancer patients.

Study design

Open, multicentre, prospective, cohort, study.

Intervention

While performing an EUS-FNA or EBUS for standard mediastinal staging, a golden fiducial marker will be placed within assessable lymph nodes. During radiotherapy preparation and delivery the motion of the lymph nodes will be monitored, using 4D-CT and 4D-CBCT scanning.

Study burden and risks

No extra invasive investigations will be performed. Placement of the fiducial markers will be performed during a regular staging procedure (with informed consent). The duration of EUS or EBUS will increase due to the marker placement. No adverse events are expected by marker placement other than the regular risks of EUS-FNA or EBUS procedure. EUS-FNA and EBUS are considered as safe staging procedures with a morbidity of < 1%
The variability of the position of the lymph nodes will be quantified by the standard 4D-CT scan during the radiotherapy treatment preparation phase and daily repeated 4D-CBCT scans during the course of treatment. Accordingly to standard procedures, CBCT scans will be made right before the first 3 fractions and thereafter weekly 4D-CBCT scans will be made. For the patients within this trail daily CBCT scanning will be performed. The total additional imaging dose associated with the additional CBCT images equals about 1% of the treatment dose. This is similar to the calculation accuracy of state of the art treatment planning systems and is thus considered to be negligible.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

postbus 90203
1006BE Amsterdam
NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

postbus 90203
1006BE Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Patient suspected with NSCLC who will undergo EUS-FNA and are planned for radical radiotherapy
• Performance status 0 to 2 (WHO scale, see Appendix B)
• Clinical indication for radical chest radiation
• Medically fit to undergo EUS-FNA or EBUS and radical chest radiation according to the treating physician
• Age: 18 years or older
• Before patient registration, written informed consent must be given according to ICH/GCP, and national and local regulations
• Participation in another study is allowed

Exclusion criteria

none

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-09-2010
Enrollment:	54
Type:	Actual

Medical products/devices used

Generic name:	Golden Fiducial marker 0.35mm by 5mm
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	11-03-2010
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	17-07-2012
Application type:	Amendment

Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL30773.031.09