Ontwikkeling van een MRI-scanningsprotocol voor het afbeelden van stadium III niet-kleincellig longkanker.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27984

Source
NTR

Health condition

1. Healthy volunteers
2. Patients with stage III NSCLC MRI

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: Funded by sponsor (UMC Utrecht)

Intervention

Outcome measures

Primary outcome

• Healthy volunteers (n=10): Quality of the scans will be assessed by rating the motion artifacts and visibility of the lung and mediastinal parenchyma.

• Patients with stage III NSCLC (n=20): Optimization of lung MRI for radiotherapy purposes (i.e. tumor delineation and motion characterization) defined by the quality of the images. Quality will be assessed by rating of the scans regarding the visibility of the primary tumor, lymph nodes and mediastinal parenchyma.

Secondary outcome

- Estimation of number of patients needed to power a study on the added value of MRI for tumor delineation
- Estimation of the number of patients needed to power a study on the characterization of tumor and lymph node motion

Study description

Background summary

Rationale: Patients with stage III non-small cell lung cancer (NSCLC) have a poor survival due to inadequate loco-regional control. Increasing the dose will lead to better loco-regional control and survival. However, with the current treatment planning strategies, increasing this dose would result in intolerable toxicity of the organs at risk (OARs, healthy tissue surrounding the tumor). Therefore, new treatment planning strategies have to be developed to improve local control and therefore overall survival of patients with stage III NSCLC. Currently, the radiation oncologist uses a combination of imaging modalities for the delineation of the lung tumor and lymph nodes: 4D- computed tomography (CT) scan, CT-scan with intravenous contrast and the positron emission tomography (PET)-CT with fluorodeoxyglucose as a radioactive tracer. However these imaging modalities have some disadvantages.In current clinical practice, large treatment volumes are irradiated. This results in an increased dose to OARs. Consequently, further increasing of the dose to the tumor would result in intolerable toxicity.
We believe that MRI can be used to improve visualization of the tumor and lymph nodes and characterize their motion, based on promising results in recent literature. MRI can potentially be used to obtain more accurate (thus smaller) treatment volumes. This will lead to a smaller dose to the OARs and enable safe dose escalation.
Unfortunately there are no MRI protocols in the literature available aimed at radiotherapy of lung cancer.

The objective of this study is twofold. We would first like to use MRI in volunteers to select the appropriate techniques for motion compensation. Furthermore, MRI settings will be sought which can be used to image lung and mediastinal parenchyma.
Second, we would like to assess the MRI sequences found in volunteers for the visualization of tumors and lymph nodes in patients with stage III NSCLC. Furthermore, we would like to assess if MRI can be used for (automatic) motion characterization of tumor, lymph nodes and organs at risk.
The sequences found in this study will be used in a future study on the added value of MRI for

radiotherapy treatment planning of stage III NSCLC, in which MRI will also be compared to PET-CT.

Objectives:
• To select the appropriate techniques to image lung and mediastinal parenchyma. Furthermore, MRI settings will be sought which can be used for motion compensation.
• To optimize and validate MRI for the visualization and motion characterization of tumor, lymph nodes and mediastinal parenchyma in patients with stage III NSCLC.

Study design: Observational study.

Study population:10 healthy volunteers and 20 patients with pathologically proven stage III NSCLC with lymph node metastases (i.e. excluding T4N0) referred to the department of Radiation Oncology.

Procedure: Healthy volunteers will undergo an MRI scan without intravenous contrast. Patients will undergo a contrast-enhanced MRI scan.

Main study parameters/endpoints:
• Healthy volunteers: Quality of the scans will be assessed by rating the motion artifacts and visibility of the lung and mediastinal parenchyma.
• Patients with stage III NSCLC: Optimization of lung MRI for radiotherapy purposes (i.e. tumor delineation and motion characterization) defined by the quality of the images. Quality will be assessed by rating of the scans regarding the visibility of the primary tumor, lymph nodes and mediastinal parenchyma.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
• Healthy volunteers will undergo an MRI scan with a maximal duration of 45 minutes. One visit to the hospital (lasting approximately 75 minutes) is required and the healthy volunteers will receive a gift voucher with a value of 25 euros. MRI-safety screening is required before the MRI scan, and consists of routine screening according to the clinical guidelines as determined by the Department of Radiology of the UMCU.
• Patients will undergo an MRI scan with a maximal duration of 45 minutes. The total visit to the department (including patient preparation, changing of clothes etc.) will last approximately 75 minutes. For determination of renal function, a recent value of the Glomerular Filtration Rate (GFR) (≤21 days) has to be available.

After proper screening, the use of MRI is safe. The use of gadolinium contrast (Gadovist) has a very low risk of contrast induced allergy.

For the patients included in the study there is no individual benefit.

Study objective

We believe that MRI can be used to improve visualization of the lung tumor and metastatic lymph nodes and to characterize their motion.

We would first like to use MRI in volunteers to select the appropriate techniques for motion

compensation. Furthermore, MRI settings will be sought which can be used to image lung and mediastinal parenchyma.
Second, we would like to assess the MRI sequences found in volunteers for the visualization of tumors and lymph nodes in patients with stage III NSCLC. Furthermore, we would like to assess if MRI can be used for (automatic) motion characterization of tumor, lymph nodes and organs at risk.

Study design

For healthy volunteers: not applicable
For patients: MRI before start of radiation treatment

Intervention

1 MRI scan, without contrast for the volunteers

1 MRI scan, with contrast for the patients

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Eligibility criteria

Inclusion criteria

Healthy volunteers:
o ≥18 years.
o Written informed consent.

Patients:
o Patients with histopathologically or cytologically proven stage III NSCLC (excluding T4N0) referred to the department of Radiation Oncology.
o ≥ 18 years.
o Written informed consent.
o Recent (≤ 21 days) GFR value available

Exclusion criteria

Healthy volunteers:
o Volunteers who meet exclusion criteria for MRI following the protocol of the department of Radiology of the UMC Utrecht.

o Patients:
o Patients who meet exclusion criteria for MRI following the protocol of the department of Radiology of the UMC Utrecht.
o Patients for whom lying still in a supine position for 45 minutes is physically too strenuous (e.g. due to orthopnea).
o Glomerular Filtration Rate (GFR) of <30 mL/min/1.73m2 (UMCU protocol ‘MRI Contra-indicaties’, Version 3 January 2013).
o Patients with nephrogenic systemic fibrosis,nephrogenicfibrosingdermopathy or severe renal insufficiency (UMCU protocol ‘MRI Contra-indicaties’, Version 3 January 2013).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	24-02-2014
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion
Date: 12-02-2014

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44655
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4235
NTR-old	NTR4380
CCMO	NL46711.041.13
OMON	NL-OMON44655

Study results