MRI for radiotherapy treatment planning of stage III NSCLC: an MRI optimization study in healthy volunteers and patients

Published: 31-01-2014
Last updated: 15-05-2024

Healthy volunteers* To select the appropriate techniques to image lung and mediastinal parenchyma. Furthermore, MRI settings will be sought which can be used for motion compensation.Patients* To optimize and validate MRI for the visualization and...

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

Summary

ID

NL-OMON44655

Source
ToetsingOnline

Brief title
MRI optimization study in stage III NSCLC

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms

Synonym
lung cancer, non-small cell lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Lung cancer, MRI, Optimization, Radiotherapy

Outcome measures

Primary outcome

* 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.

Secondary outcome

The results of this optimization study will be used for the power analysis of consecutive studies.

Study description

Background summary

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.

Study objective

Healthy volunteers
* To select the appropriate techniques to image lung and mediastinal parenchyma. Furthermore, MRI settings will be sought which can be used for motion compensation.

Patients
* 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: 20 volunteers will receive an MRI-scan without contrast and 20 patients with stage III NSCLC will receive a contrast-enhanced MRI-scan.

Study burden and risks

* 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) (* 3 months) 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.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Healthy volunteers
- *18 years
- written informed consent;Patients:
- patients with histopathologically or cytologically proven stage III NSCLC (excluding T4N0) referred to the department of Radiation Oncology
- * 18 years
- written informed consent
- recent (* 3 months) GFR value available

Exclusion criteria

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

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):	20-03-2014
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	31-01-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-03-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	13-10-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-07-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-04-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-11-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	31-08-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27984
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL46711.041.13
OMON	NL-OMON27984