

Evaluation of radiation induced pulmonary hypertension using MRI in stage III NSCLC patients treated with chemoradiotherapy. A Pilot Study.

Published: 21-09-2011

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The objective is to test the hypothesis that radiotherapy for lung cancer induces an increase in pulmonary artery pressure.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract neoplasms
Study type	Observational non invasive

Summary

ID

NL-OMON35880

Source

ToetsingOnline

Brief title

Radiation induced pulmonary hypertension

Condition

- Respiratory tract neoplasms
- Vascular hypertensive disorders

Synonym

Lung cancer, pulmonary hypertension

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

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

Intervention

Keyword: Cardiac MRT, Pulmonary Hypertension, Radiotherapy

Outcome measures

Primary outcome

Changes in pulmonary artery pressure 6 and 12 weeks after completion of chemoradiotherapy reference to baseline using cardiac MRI.

Secondary outcome

- Pulmonary artery velocity; right ventricle (RV) dimensions and RV-function; pulmonary artery distensibility 6 and 12 weeks after completion of chemoradiotherapy reference to baseline.
- The assessment of RV-dimensions and RV-function 6 and 12 weeks after chemoradiotherapy reference to baseline.
- The incidence of clinical signs of radiation pneumonitis according to SWOG-criteria 6 weeks after completion of treatment
- The incidence of radiological signs of pulmonary fibrosis according to CTCAE4.0 12 weeks after completion of treatment .

Study description

Background summary

In the radiotherapeutic treatment of lung cancer, the dose that can be safely applied to the tumour is limited by the risk of radiation induced lung damage. This damage is characterized by parenchymal damage and vascular damage. In rats, we have found that radiation-induced vascular damage results in increased pulmonary artery pressure. Interestingly, the consequent loss of pulmonary function could be fully explained by this increase in pulmonary artery pressure. We hypothesize that also in patients a radiation induced increase in pulmonary artery pressure can be observed after radiotherapy, which may contribute to the development of radiation pneumonitis.

Study objective

The objective is to test the hypothesis that radiotherapy for lung cancer induces an increase in pulmonary artery pressure.

Study design

Observational pilot study.

Study burden and risks

If safety procedures are followed, with appropriate screening for contra-indications, repeated MRI poses no risk to patients.

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

- . WHO PS 0-2
- . Stage IIIA or IIIB non-small cell lung cancer
- . Planned for 25 x 2.4 Gy, with concomitant chemotherapy

Exclusion criteria

Contra-indications for undergoing MRI-scans;;Absolute contra-indications:

- ICD (implanteerbare cardioverter-defibrillator)
- All pacemakers except for the SureScan (Medtronic) (under conditions) ;Relative contra-indications
- Prior pacemaker wires
- Clips, stents
- Non-removable hearing aids
- Non-removable insulin pumps
- Nerve stimulators
- Metal fragments in the eyes
- Inflatable breast implants
- Severe claustrophobia

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 03-09-2012
Enrollment: 10
Type: Actual

Ethics review

Approved WMO
Date: 21-09-2011
Application type: First submission
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO
Date: 12-11-2012
Application type: Amendment
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	NL37007.042.11