DW-MRI in mediastinal restaging after concomitant chemoradiotherapy and prognosis of trimodality treatment for stage IIIA/B NSCLC with mediastinal lymph node metastases and without supraclavicular lymph node metastases ; NSCLC Stadium IIIA/B N2/3

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This study aims to investigate the feasability to use DW-MRI for mediastinal restaging after concomitant chemoradiotherapy and the feasability to predict whether or not mediastinal downstaging will be achieved during concomitant chemoradiotherapy...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON43810

Source ToetsingOnline

Brief title MRI in trimodality treatment for locally advanced NSCLC

Condition

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

Synonym

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Lungcancer, Non-small cell lung cancer

Research involving Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis Source(s) of monetary or material Support: UMCU afdeling radiotherapie

Intervention

Keyword: DW-MRI, Non-small cell lung cancer, Restadiering, Trimodality treatment

Outcome measures

Primary outcome

Main study parameters/endpoints: Determination of the feasibility to use

DW-MRI in the evaluation of treatment response during and after

chemoradiotherapy treatment for locally advanced NSCLC compared to the

pathological specimen as gold standard.

Secondary outcome

nvt

Study description

Background summary

For the group of patients with non-small cell lung cancer with mediastinal lymph node metastasis the standard treatment consists of concomitant chemoradiotherapy, additional surgery can be considered for selected patients (trimodality treatment). Patients seem to benefit from surgery after chemoradiotherapy when mediastinal downstaging or complete response is achieved. Mediastinal restaging is difficult and imaging and invasive restaging methods show a high rate of false negative results. Improvement of radiological re-staging might improve selection of patients who seem to benefit from surgery after chemoradiotherapy and reduce the need of invasive restaging techniques.

Study objective

This study aims to investigate the feasability to use DW-MRI for mediastinal restaging after concomitant chemoradiotherapy and the feasability to predict whether or not mediastinal downstaging will be achieved during concomitant chemoradiotherapy in patients with non-small cell lung cancer with mediastinal lymph node involvement, without supraclavicular lymph node involvement, stage III A/ B N2/3.

Study design

Prospective non-randomized cohort study, diagnostic study

Study burden and risks

For study purposes the patients will undergo three extra MRI scans and one FDG-PET scan. The MRI scans will be performed with an intravenous contrast agent (gadolinium). For the FDG-PET there is an irradiation load of 3-4 mSv, this involves mild risk for the patients. These scans will be scheduled in combination with standard appointments. For the patients included in the study, there is no individual benefit.

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 between 18-76 years old, diagnosed with locally advanced NSCLC with pathologic proven (cytology or histology) mediastinal lymph node metastasis, without supraclaviculair lymph node metastasis, stage III A and B N2/3. Patients are planned for treatment with concomitant chemoradiotherapy.

Exclusion criteria

Supraclaviculair lymph node metastasis or distant metastasis Other potential curative treatment options Mixed tumor types with small cell lung cancer Expected need for pneumonectomy right lung Participation in other trial with investigational drug or treatment modality Contraindications MRI

Study design

Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	50
Туре:	Anticipated

Ethics review

Approved WMO Date: Application type: Review commission:

20-12-2016 First submission MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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 CCMO **ID** NL54489.100.16