Cardiac changes after stereotactic radiotherapy for early stage NSCLC cancer or lung metastasis - HALO

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON55624

Source
ToetsingOnline

Brief title
HALO

Condition

- Cardiac disorders, signs and symptoms NEC
- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
cardiac toxicity, lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: KWF 11964

Intervention

Keyword: cardiac changes, lung cancer, radiotherapy

Outcome measures

Primary outcome

Investigate if changes in cardiac condition (cardiac arrhythmias, fibrosis,

hemodynamic function change and pericarditis) can be visualised and quantified.

A negative change of more than 5% between pre-and post-treatment measurements

is considered toxicity.

Secondary outcome

- Investigate if local fibrosis is associated to local dose.

- Investigate if morphology changes are visible during treatment (optional)

Study description

Background summary

For lung cancer patients that receive thoracic irradiation, cardiac toxicity was not considered to play a role, because it was expected to occur many years after treatment. However, recently several studies have shown higher death rates for lung cancer patients receiving higher cardiac doses, possibly due to cardiac toxicity. Most knowledge on cardiac toxicity that we have is based on patients that receive conventionally fractionated radiation treatment, where the heart receives a relatively low dose of radiation. For patients that receive stereotactic body radiation therapy (SBRT), which gives high fraction doses, the heart may receive peak doses of radiation, especially for centrally located tumours. This type of therapy is standard of care for early stage lung cancer patients, with very high local control that is similar to surgically treated patients. In order to improve the radiation treatment for these early stage lung cancer patients, detailed knowledge on cardiac toxicity in these patients is necessary.

Study objective

We aim to optimize the radiation treatment of early stage lung cancer patients.

Cardiac sparing is possible, but it comes at the cost of an increased mean lung dose. Without proof of cardiac toxicity, cardiac sparing will not be (routinely) applied. Therefore, we need detailed understanding of the type of toxicity and the location of these toxicities for patients who receive high fraction doses. These have not been measured in this category of patients before, therefore our primary research question is: is it possible to measure changes in cardiac condition 3 or 12 months after radiotherapy, with respect to cardiac arrhythmias, tissue fibrosis, hemodynamic function change and pericarditis? If indeed cardiac changes can be measured, these results will be used to set up a larger trial to determine a dose effect relation for cardiac toxicity in early stage lung cancer patients treated with high fraction doses.

Study design

Twenty five patients with early stage lung cancer who are treated with SBRT will be enrolled in an observational prospective cohort study and treated following standard clinical practice. Condition of the heart will be examined before treatment using ECG, cardiac MRI, echocardiography and blood biomarkers. These tests will be repeated 3 and 12 months after treatment.

Study burden and risks

The patient will have 3 sessions with several diagnostic tests; ECG, cardiac MRI, echocardiography and blood sampling, and will fill out 3 questionnaires. Limited side effects of these tests are expected. Cardiac tests will be evaluated by a cardiologist and dedicated radiologist and reported to the radiation oncologist who will inform the patient and refer to the cardiologist if needed. The burden for these patients will be, next to the time spent for the diagnostic tests and travel time; an intravenous blood sampling and administration of MRI contrast agent. The additional time spent for diagnostic tests per session are: echo (30 min), ECG (5 min), vena puncture (5 min) and MRI (45 min) + time in the waiting room. Filling out the 3 questionnaires will take 15 min each.
The possible benefit for the patient is the extensive cardiac screening. Should a problem come to light, the patient will be referred to the cardiologist. Results from this patient cohort are directly relatable to all early stage NSCLC who are treated with SBRT, and possibly oesophageal cancer patients as well. Should this study show that cardiac dose causes cardiac toxicity in this time frame, we should aim to improve treatment for all patients who are comparable. Ergo; patients who receive cardiac dose because of their tumour location, and who are generally unfit for surgery because of their physical condition (early stage NSCLC patients and oesophageal cancer 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

In order to be eligible to participate in this study, the patient must meet all of the following criteria:
- Receive SBRT treatment for stage 1A-2B NSCLC or for a solitary lung metastasis of a solid tumor
- Closest distance between edge of tumor and heart < 3 cm, measured on the diagnostic CT scan using lung window setting (W*=*1600 and L*=**600)

Exclusion criteria

- a pacemaker/implantable cardioverter-defibrillator (ICD), as these cannot be scanned in MRI

- a renal function below GFR <60 ml/min/1.7m2, because administration of MRI contrast will then not be desirable

Study design

Design

Study phase:	3
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-01-2021
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	22-10-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	18-02-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	21-12-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	

Date:	10-06-2021
Application type:	Amendment
Review commission:	METC NedMec

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
ClinicalTrials.gov	NCT03984019
CCMO	NL69372.031.19