Monitoring radiation induced cardiac damage by blood markers

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The main objective of this study is to find a correlation between the rise in NT pro BNP level and the radiation dose given to the heart.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Myocardial disorders
Study type	Observational invasive

Summary

ID

NL-OMON42221

Source
ToetsingOnline

Brief title
CARD study

Condition

- Myocardial disorders
- Malignant and unspecified neoplasms gastrointestinal NEC
- Respiratory tract neoplasms

Synonym
radiation induced cardiac damage

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cardiac, radiotherapy, toxicity

Outcome measures

Primary outcome

Percentage of rise of the level of NT pro BNP after radiotherapy

Secondary outcome

• A new diagnosis of: heart failure, myocardial infarction or a newly diagnosed rhythm disorder will be scored as a cardiac event. Myocardial ischaemia requiring intervention and changes in cardiac medication in case of deterioration of known heart failure will be analysed by a cardiologist to decide whether or not to score this as an event. Events will be scored according the CTCAE 4.2 criteria.

• Percentage of rise of hs-TNT during or after treatment

Study description

Background summary

Radiation induced cardiac toxicity after treatment for intrathoracic tumours is a clinically relevant problem. So far, no clinical prediction models exist for cardiac toxicity. In particular, the relationship between radiation dose parameters and the risk of cardiac toxicity remains to be determined. Clinical prediction models for cardiac toxicity are difficult to obtain, e.g. due to long latency time. Therefore, objective surrogate markers, for cardiac toxicity such as NT pro BNP and hs-TNT, as obtained during and after treatment may be of great value.

Study objective

The main objective of this study is to find a correlation between the rise in NT pro BNP level and the radiation dose given to the heart.

Study design

prospective evaluation of blood parameters

Study burden and risks

Participation in this study does not involve any additional risk to patients.
For most patients blood sample collection during treatment can be done simultaneously during blood sample collection for regular check.
Extra punctures are required three to four times during follow up visits as routine blood sample collection for these patient groups is usually not performed.
Blood withdrawal may result in local tenderness or hematoma, which are self-limiting.
Risk models predicting cardiac damage after radiotherapy will improve decision making for radiation treatment planning and techniques. Surrogate early endpoints will improve the model and select patients who are at higher risk for developing cardiac events. Those patients are probably candidates for early cardiac evaluation as preventive measures can be taken.

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 with esophageal or non small cell lung cancer with an curative indication for radiotherapy, with or without chemotherapy, with or without surgery.

Exclusion criteria

prior radiotherapy to the chest, treatment with palliative intent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-09-2015
Enrollment:	87
Type:	Actual

Ethics review

Approved WMO

Date:	23-04-2015

Application type:	First submission
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	NL50262.042.14