A PROspective, explorative cohort study to correlate CARdiac BIomarkers with late cardiac toxicity induced by radiotherapy alone or combined with anthracycline chemotherapy for hodgkin lymphoma (PROCARBI)

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29157

Source
Nationaal Trial Register

Brief title
PROCARBI

Health condition

Previous history of Hodgkin or mediastinal non-Hodgkin lymphoma treated with mediastinal radiotherapy with or without anthracycline-containing chemotherapy

Sponsors and support

Primary sponsor: Department of radiotherapy and cardiology of Erasmus MC
Source(s) of monetary or material Support: Department of radiotherapy and cardiology of Erasmus MC

Intervention

Outcome measures

Primary outcome

The primary objective is to evaluate in terms of sensitivity, specificity and predictive value a panel of cardiac biomarkers for the early detection of an increase in cardiac symptoms for HL and (selected) NHL long-term survivors. The panel of biomarkers will be compared to an evaluation including clinical assessment, ECG, heart US and PROMs.

Secondary outcome

– To describe the early symptoms of long-term cardiac toxicity induced by radiotherapy with or without chemotherapy for HL and NHL patients.
– Develop a screening tool for the early detection of cardiac toxicity including biomarkers, imaging tests and PROMs.
– Difference in score of the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) and the Seattle Angina Questionnaire (SAQ-7).
– To evaluate the value of cardiac MRI as an objective diagnostic tool for mediastinal radiotherapy and/or chemotherapy induced cardiac toxicities.
– To evaluate the dose effect relationship between the detected increase in cardiac symptoms and various late severe cardiac toxicities.
- Evaluation of the radiation with/without anthracycline dose effect relationship, and the impact of other factors of risk (age at treatment, gender, body mass index (BMI), hypertension, diabetes, dyslipidaemia, and tobacco use).

Study description

Background summary

Rationale: Cardiac toxicities, mainly myocardiopathy, valvular heart disease and coronary heart disease, are unwanted delayed side effects after chemotherapy and/or mediastinum radiotherapy in Hodgkin Lymphoma patients and breast cancer patients. There are national guideline for follow-up of Hodgkin and selected non-Hodgkin lymphomas. Those guidelines include tests focusing on early detection of heart failure, including a physical examination, ECG, blood test to measure NT-proBNP and other risk factors of CHD, and a cardiac ultrasound every 5 years. The diagnosis of heart failure is generally only possible when symptoms have become manifest and the heart disease cannot be reversed. Biomarkers have the potential to screen at low cost subtle changes in the heart that may reflect or predict early adverse changes before they become clinically evident. Use of serial biomarker measurements (including NT-proBNP, ST2, GDF15, Galectin 3, and hsTn) during follow-up may provide information on individual patterns of change and may contribute to prevention,

in taking early measures to prevent further deteriorating of the cardiac condition. In addition, adverse changes in the heart may also be confirmed by adding other imaging techniques to heart US such as cardiac MRI before clinical symptoms occur. Finally, using patient's reported outcome measures (PROMs) questionnaire including the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) and the Seattle Angina Questionnaire (SAQ-7) it may be possible to correlate those objective findings and changes in these findings with the patient's cardiac health status and with the biomarkers.
Objectives: We hypothesize that there is a combination of biomarkers that is a predictor of early development of cardiac toxicity from radiotherapy and chemotherapy in a population at risk of developing late clinically manifest cardiac toxicity after previous mediastinal radiotherapy alone or combined with chemotherapy. We also hypothesize that imaging tests including functional US and cardiac-MRI could objectively confirm those early developments, and that their clinical impact could be identified using PROMs in addition to the anamnesis and physical examinations.
Study design: This study is a prospective explorative cohort study for patients in long-term follow-up after mediastinal radiotherapy alone or combined with chemotherapy for Hodgkin and selected non-Hodgkin lymphoma to assess the correlation between a panel of blood biomarkers, cardiac US and MRI imaging, and PROMs.
Study population: All patients > 18 years, who have been treated for Hodgkin or non-Hodgkin Lymphoma with radiation of the mediastinum with or without anthracycline-containing chemotherapy with at least 5 years of disease free survival.
Intervention: There is a national prospective cohort of lymphoma patients currently followed by the BETER consortium. The current study will include patients at one of these follow-up visits and add a blood sample, PROMs, and cardiac-MRI, in addition to the scheduled measurements at the inclusion visit and the next visit two years later.

Study objective

We hypothesize that the combination of biomarkers (e.g. NT-proBNP, ST2, GDF15, Galectin 3, hsTn) is an early predictor of cardiac toxicity from radiotherapy and chemotherapy in a population at risk of developing late cardiac toxicity after previous radiotherapy alone or combined with chemotherapy. We also hypothesize that imaging tests including functional US (all patients) and cardiac MRI (up to the first consecutive 80 patients) can objectively confirm those early signs of cardiac toxicities, and that the clinical impact can be assessed using PROMs.

Study design

2 points 2 years apart

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

• Previous history of Hodgkin or mediastinal non-Hodgkin lymphoma treated with mediastinal radiotherapy with or without anthracycline-containing chemotherapy
• Planned visit at the BETER clinic
• Written informed consent
• Age >= 18 years
• A minimum of 5 years of disease free survival

Exclusion criteria

• Not currently under treatment for malignant disease (unless basal cell carcinoma).
• Patients who already underwent a surgical intervention for cardiac problems, such as heart valve replacement or a coronary artery bypass grafting (CABG).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2018
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	14-08-2019
Application type:	First submission

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
NTR-new	NL7958
Other	METC Erasmus MC : MEC-2017-505

Study results