Cardiac dysfunction and undiagnosed heart failure in women as a long term effect of the treatment of breast cancer in an unselected primary care setting

Published: 28-02-2013
Last updated: 26-04-2024

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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-OMON39592

Source
ToetsingOnline

Brief title
Long term effect of the treatment of breast cancer: cardiac dysfunction

Condition

- Cardiac disorders, signs and symptoms NEC
- Haematopoietic neoplasms (excl leukaemias and lymphomas)

Synonym
cardiac dysfunction, heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Stichting Pink Ribbon; Zorgverzekeraar De Friesland

Intervention

Keyword: cardiac dysfunction, chemotherapy, long term follow-up, radiotherapy

Outcome measures

Primary outcome

The primary outcome of this study is the proportion of women with a systolic

and / or diastolic cardiac dysfunction at echocardiography.

Secondary outcome

The secondary outcome is heart failure: a combination of clinical complaints

and objective abnormalities at physical examination, laboratory examination or

echocardiography.

Study description

Background summary

It is important to assess whether there are women with yet unknown cardiac dysfunction or heart failure as early diagnosis provides the opportunity for early treatment thus preventing deterioration of cardiac function and improving the prognosis of patients. To get a reliable estimate of the prevalence of these problems it is important to get data from an unselected population.

Study objective

The aim of our study is to assess the prevalence of cardiac dysfunction and undiagnosed heart failure in women registered in general practice with a history of breast cancer who received chemotherapy and / or radiotherapy as compared to a matched female control population.

Study design

The method of this study is a cross-sectional design in which women in general practice who have been treated for breast cancer with chemo and / or radiotherapy and an age and general practitioner (GP) matched female control population will be screened on the presence of cardiac dysfunction and heart failure.

Study burden and risks

The risks of the study are minimal, as all investigations are non-invasive, except for the vena puncture.
The burden of the study for the participants comprises of one visit to the GP*s office to fill in questionnaires and for a limited physical examination (blood pressure, auscultation of the heart), a visit to the laboratory for blood tests and electrocardiography, and a visit to the hospital for echocardiography.

The consent form will include a paragraph on incidental findings and the option to refuse to be informed about any unexpected abnormality. If the patient want to be informed on (incidental) findings they can fill in on the consent form in what way this will take place (e.g. via their GP).

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
- Women with breast cancer who were treated with chemotherapy and/or radiotherapy in 2006 or before (minimal follow-up period of five years) and after 1970 (due to old fashion treatment or incomplete data)
- Written informed consent
Controls
- Female patients without a history breast cancer, registered in the general practice of the case-patient, matched on age
- Written informed consent

Exclusion criteria

Patients and controls
- Patients over 80 years of age at the time of diagnosis (because of an expected high frequency of CVD and a life expectancy of less than 10 years in this age-group)
- Any history of other cancer (possibility of chemotherapy and / or radiotherapy)
- Any history of receiving chemotherapy for other indications
- Women who are unable to participate (e.g. terminally or mentally ill)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-06-2013
Enrollment:	700
Type:	Actual

Ethics review

Approved WMO Date:	28-02-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-05-2013
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	NL42193.042.12