Identifying subgroups with High cArdiovascular Risk in Breast cancer survivORs (HARBOR)

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- to evaluate the prevalence of (sub)clinical CVD, cardiovascular risk factors and metabolic abnormalities among BC survivors treated with and without anthracyclines in two groups at (a) 5-7 years and (b) 10-12 years after diagnosis;- to...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON53099

Source
ToetsingOnline

Brief title
HARBOR

Condition

- Heart failures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
heart failure, left ventricular dysfunction

Research involving
Human

Sponsors and support

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

Intervention

Keyword: anthracyclines, breast cancer survivors, cardiovascular disease risk, late effects

Outcome measures

Primary outcome

The difference in (sub)clinical cardiovascular damage between patients treated with and without anthracyclines, as measured by left ventricular function parameters.

Secondary outcome

Secondary parameters are the difference in the prevalence of cardiovascular risk factors, the difference of biochemical measurements related to cardiovascular risk and function, the difference in reproductive history and menopausal status, the difference in quality of life, anxiety, depression and fatigue, the difference in cardiovascular function tests, the difference in physical activity, the difference in cognitive functioning, the difference in presence of cellular senescence and the difference in DNA profiles and telomere length between patients treated with and without anthracyclines.

Study description

Background summary

Breast cancer (BC) incidence is increasing, while mortality from BC is decreasing. Since the life expectancy of BC patients is improving, the evaluation of treatment-associated cardiovascular disease (CVD) in BC survivors is becoming increasingly important. An excess risk of CVD, mainly due to coronary heart disease (CHD), has been observed after radiotherapy (RT) as administered in the 1960s-1980s. Anthracycline-containing CT and trastuzumab are known to induce acute cardiotoxicity, especially congestive heart failure (CHF). However, the long-term risks of CVD after anthracycline-containing CT,

trastuzumab, hormonal therapy (HT) and contemporary RT techniques have hardly been examined. Furthermore, the potential interaction of these treatment modalities has not been well addressed, and there is limited knowledge about the contribution of classic cardiovascular risk factors and the metabolic syndrome to risk and severity of treatment-associated CVD in BC survivors.

Study objective

- to evaluate the prevalence of (sub)clinical CVD, cardiovascular risk factors and metabolic abnormalities among BC survivors treated with and without anthracyclines in two groups at (a) 5-7 years and (b) 10-12 years after diagnosis;
- to prospectively evaluate changes in prevalence of (sub)clinical CVD, cardiovascular risk factors and metabolic abnormalities after two years in the same patients.

Secondary objectives are to evaluate the predictive role of newly developed markers for CVD and to evaluate the effects of other BC treatment modalities (radiotherapy, immunotherapy, hormonal therapy), psychosocial outcomes (depression, fatigue, quality of life), endocrine function, menopausal status induced by breast cancer treatment and cellular senescence on the risk of developing (sub)clinical CVD. Examining cognitive functioning in the different groups is also a secondary objective.

Study design

Multicenter (AVL and UMCG) cross-sectional cohort study with prospective monitoring of the same cohort.
Eligible study candidates will receive an invitation letter through their (former) treating physician. Candidates willing to participate are asked to provide their informed consent and fill in an online questionnaire. After receiving the informed consent participants are scheduled for their first visit at the outpatient clinic. At the study visit blood will be drawn at the laboratory and additional information on medical history, current medication and current status is obtained by the research physician. A full physical examination will be performed, including skin autofluorescence. Furthermore an echocardiography and echography of the carotid and femoral artery are planned and the participant is asked to provide us with a urine sample. At the end of the program, participants will again meet with the research physician. Besides, the participant will be asked to make online cognitive tests and fill in a questionnaire about cognitive functioning at home, using the Amsterdam Cognition Scan tool.
The format of the second study visit, two years after the first visit has the same format. The participant will receive an invitation letter for the second visit at the outpatient clinic and a request to fill in an online questionnaire. Participants unwilling to participate in the second study visit can decline by contacting the study coordinator, this is explained in the

invitation letter. At the outpatient blood will be drawn, urine collected and the same tests will be performed.

Study burden and risks

The burden of participation comes from the two visits at the outpatient clinic. Patients will fill in questionnaires, make cognitive tests, undergo physical examination and cardiovascular assessment. ECG, echocardiography, echography of the carotis and femoralis and skin autofluorescence are non-invasive tests. A maximum of 110ml blood is drawn per visit. Cardiovascular risk assessment could be beneficial for the participant, since CVD and cardiovascular risk factors will be treated if necessary.

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

- female;
- early invasive BC (TNM stage I - III);
- diagnosed and/or treated in the AVL or UMCG;
- treated 5 - 7 years or 10 - 12 years ago;
- aged 40-50 years at time of therapy;
- signed written informed consent.

Exclusion criteria

- history of RT or CT unrelated to BC;
- currently under treatment for BC recurrence or second malignancy (including contralateral BC) other than non-melanomatous skin cancer or curatively treated carcinoma in situ of the cervix;
- history of cardiac disease (CHF, acute coronary syndrome, coronary revascularization procedure, symptomatic valvular dysfunction, cardiomyopathy or congenital heart defect) before diagnosis and treatment for BC;
- mental disability or psychological condition potentially hampering compliance with the study protocol;
- insufficient understanding of the Dutch language.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-02-2015

Enrollment:	628
Type:	Actual

Ethics review

Approved WMO Date:	08-12-2014
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	24-03-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-10-2022
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	NCTnummernognietbekend.
CCMO	NL49405.031.14