Breast cancer Long-term Outcomes on Cardiac functioning: a longitudinal study

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

Summary

ID

NL-OMON51722

Source
ToetsingOnline

Brief title
BLOC-II

Condition

- Cardiac disorders, signs and symptoms NEC
- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
cardiac dysfunction, heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Breast Cancer, Cardiac dysfunction, long term adverse effects, primary care

Outcome measures

Primary outcome

Left ventricular systolic and diastolic cardiac dysfunction. Systolic cardiac dysfunction is defined as a LVEF <54%. Diastolic cardiac dysfunction is defined as e* lateral or e* septal at 2.5% below the normal range for age group.

Secondary outcome

Clinically used LVEF cut-off points <45% and <50%.

- Severe diastolic dysfunction as defined by impaired relaxation in combination with an increased left atrial volume index (LAVI; defined as >= 34 ml/m2).
- Diagnoses of cardiovascular disease
- Rate of deterioration of cardiac function by change in LVEF
- Global Longitudinal Strain (GLS)
- Biomarkers (e.g. NT-proBNP)

Covariates assessed during new measurement

- Patient characteristics: age, BMI, menopausal state, smoking behavior, physical activity level,
- Changes in lifestyle
- Symptoms of anxiety, depression and fatigue (HADS & MFI-20)
- Use of cardiovascular medication at time of BLOC-II study

Background variables / predictors (assessed during BLOC-I study)

- Treatment characteristics: administered chemotherapy regimens, cumulative

dosages, antihormone treatments, and radiotherapy site (left or right), RT

dosage on LV cardiac substructures

- Cardiovascular risk factors

- Use of cardiovascular medication

Study description

Background summary

In addition to surgery, effective breast cancer (BC) treatment typically requires chemotherapy, radiotherapy, or both. However, it is still unclear whether patients with BC are at increased risk of long-term cardiac dysfunction due to the adverse effects of these therapies. In a cross-sectional study in primary care, we compared cardiac dysfunction between 350 BC survivors and 350 age- and GP- matched controls without cancer. We found that BC survivors were at increased risk of mild systolic cardiac dysfunction (left ventricle ejection fraction: LVEF< 54%). By contrast, there was no significant difference in an LVEF < 50% or in diastolic dysfunction. To date it remains uncertain whether the mild or subclinical dysfunction we observed predicts further cardiac deterioration. Consequently, the translation of these results into guidelines for the daily practice of the GP is unclear.

Study objective

The aim of the here proposed study (BLOC-II) is to clarify whether cardiac function in survivors of BC should be monitored by GPs. We expect to clarify whether an unselected population of long-term BC survivors is at increased risk of developing cardiac dysfunction, whether in this group at-risk subgroups exists, and what factors are associated with the highest risk

Study design

We propose a new assessment of cardiac function among women included in the BLOC-I study. This produces a longitudinal matched cohort design consisting of two cohorts in primary care.

Study burden and risks

Patients are asked to complete a one-time questionnaire and make a one-time

visit to the hospital for echocardiography and blood sampling. The risk is negligible.

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 the current BLOC-II study, we will invite all women who previously took part in the BLOC-I study. Inclusion criteria of that study were: females diagnosed with stage I-III BC at least five years ago or local or locoregional recurrence of BC at least five years ago; treatment with chemotherapy and/or radiotherapy. BC survivors were matched with women of the same age (±1 year) who had the same GP, but who had no history of cancer or cancer treatment (chemotherapy or radiotherapy)

Exclusion criteria

Patients unfit to travel to the hospital or fill out questionnaires due to severe mental or physical illness, based on assessment by their GP, will be excluded.

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-10-2022
Enrollment:	455
Type:	Actual

Ethics review

Approved WMO

Date:	05-07-2022
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	NL81110.042.22