Change of cognitive function and brain structure in long-term breast cancer survivors

Published: 06-05-2020
Last updated: 08-04-2024

To determine the difference in change over time of cognitive function and brain magnetic resonance imaging (MRI) measurements between breast cancer survivors and cancer-free individuals.

Ethical review	Approved WMO
Status	Pending
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON50155

Source
ToetsingOnline

Brief title
Cognitive function in breast cancer survivors

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Structural brain disorders
- Cognitive and attention disorders and disturbances

Synonym
Cognitive deficits, memory and concentration problems

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: KWF

Intervention

Keyword: Brain structure, Breast cancer, Cognitive function

Outcome measures

Primary outcome

1. The difference in change over time of cognitive function between breast cancer survivors and cancer-free individuals

2. The difference in change over time of brain MRI measurements between breast cancer survivors and cancer-free individuals

Secondary outcome

1. The difference in change of subjective memory complaints between breast cancer survivors and cancer-free individuals

2. The predictive value of cognitive function at the first assessment for cognitive function at follow-up measurement among breast cancer survivors

3. The predictive value of subjective memory complaints at the first assessment predict cognitive function at follow-up measurement among breast cancer survivors

4. The difference in risk of dementia between breast cancer survivors and cancer-free individuals.

5. The difference in change of inflammatory markers between breast cancer survivors and cancer-free individuals.

6. The relation between cognitive function and inflammatory markers in breast cancer survivors and cancer-free individuals.

Study description

Background summary

Non-central nervous system cancer patients frequently report cognitive problems that persist well into the survivorship period. Several studies have shown that cognitive function is affected by cancer and cancer treatment, but the course of cognitive decline is less well understood. Two hypotheses regarding the trajectory of cognitive decline have been proposed, i.e., 1) phase shift hypothesis, with impaired cognitive function shortly after cancer treatment, followed by a trajectory of cognitive decline that parallels the cognitive trajectory of cancer-free individuals and 2) accelerated aging hypothesis, with the trajectory of cognitive decline among cancer patients having a steeper slope, compared to the cognitive trajectory of cancer-free individuals.

Study objective

To determine the difference in change over time of cognitive function and brain magnetic resonance imaging (MRI) measurements between breast cancer survivors and cancer-free individuals.

Study design

Cohort study.

Study burden and risks

Participants will be tested once. The examinations are similar to those performed in 2008 and 2009, and will last 135 minutes. They include measurements of weight, length, and blood pressure, a blood sample draw, an interview, neuropsychological tests, and brain MRI. The patient has to lie still in the MRI scan which can be inconvenient. The scan produces noise, which is effectively reduced by using earplugs and headphones. When standard safety rules are applied, no risks exist for the patient. Ample experience with patient populations and participants from the Rotterdam Study have indicated that this procedure is feasible and is not too burdensome. Knowledge about the trajectory of cognitive decline may aid in prevention and treatment of cognitive impairment in cancer patients.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066 CX
NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Breast cancer survivors who participated in our previous study (NL18761.031.07).
Inclusion criteria in our previous study were:
female
treatment with adjuvant CMF chemotherapy for breast cancer between 1975 and 1995
age between 50 and 80 years
sufficient proficiency in Dutch language

Exclusion criteria

No exclusion criteria will be applied for the current study. For our previous study the following exclusion criteria were applied:
use of endocrine therapy
contra-indications for MRI scan
tumor relapse
metastases

second primary tumor

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	28-06-2020
Enrollment:	120
Type:	Anticipated

Ethics review

Approved WMO Date:	06-05-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	06-05-2020
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL72396.031.20