Unravelling brain mechanisms of cognitive impairment in breast cancer patients during adjuvant endocrine treatment

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Primary Objective: Does long-term endocrine adjuvant treatment for breast cancer lead to structural changes in the brain and to functional changes in brain-wide networks, and do these changes correlate with cognitive impairment induced by the...

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

Summary

ID

NL-OMON37354

Source
ToetsingOnline

Brief title
Effects of hormonal treatment for breast cancer on brain and cognition

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast disorders

Synonym
breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: Ministerie van OC&W,In eerste instantie betreft het een stage project van een student technische geneeskunde. Een projectaanvraag is ingediend bij kwf kankerbestrijding.

Intervention

Keyword: adjuvant therapy, brain imaging, breast cancer, cognitive impairment

Outcome measures

Primary outcome

Neuropsychological measures that quantify cognitive functioning, and parameters

derived from brain imaging methods (MEG and fMRI).

Secondary outcome

n.a.

Study description

Background summary

Cognitive impairment is frequently reported by breast cancer patients during adjuvant endocrine treatment and has an important negative impact on quality of life and treatment adherence. Identification of functional changes in the brain that lead to cognitive dysfunction in breast cancer patients can not only serve a theoretical understanding of this important side effect, but can also provide an objective biological marker supporting the diagnosis. This may eventually lead to new treatment options for cognitive dysfunction. Also, the development of biological markers which correlate with a patient*s susceptibility to cognitive changes may help to identify patients at risk for cognitive impairment and thus help to individualize adjuvant endocrine treatment.

Study objective

Primary Objective: Does long-term endocrine adjuvant treatment for breast cancer lead to structural changes in the brain and to functional changes in brain-wide networks, and do these changes correlate with cognitive impairment induced by the treatment? Secondary Objective(s): Do pre-treatment structural

and dynamic properties of brain-wide networks predict treatment induced cognitive impairment?

Study design

Observational, longitudinal study.

Study burden and risks

The experimental protocol will exist of neuropsychological tests, an MEG measurement, and an (f)MRI measurement. The total duration is approximately 3.5 hours. The subjects will be measured twice at an interval of ~6 months. Considering the extensive exclusion criteria, the screening procedure, and constant monitoring of the subjects we do not expect (S)AE side effects. MEG and MRI measurements themselves do not pose any risk, if appropriate precautions are taken. The noise and the relative confined space of the MRI scanner may cause discomfort to some subjects. MEG measurements are silent and take place in a less confined space, and are even less likely to cause discomfort.

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

* Women of age * 18 years.
* Histologically/cytologically confirmed adenocarcinoma of the breast followed by intended curative surgery and if indicated, also radiotherapy and chemotherapy.
* ER + and/or PgR + receptor status.
* Indication for treatment with tamoxifen or anastrozole according to the Dutch guidelines.
* Disease-free, as defined by the absence of somatic disease activity parameters.
* Accessible for follow-up for duration of study.
* Karnofsky 80-100.
* Written informed consent.

Exclusion criteria

* Palliative treatment or inflammatory breast cancer .
* Evidence of distant metastasis (M1).
* Concomitant or previous malignancies except for adequately treated carcinoma in situ of the uterine cervix or basal squamous cell carcinoma of the skin.
* Hormone Replacement Therapy for treatment of menopausal symptoms, not stopped at least 4 weeks prior to inclusion in the study.
* Current psychological or psychiatric treatment.
* Treatment with anti-depressive drugs, anti-epileptic drugs, benzodiazepines.
* Insufficient command of the Dutch language to fill out questionnaires.
* Contra-indication for MR examinations (e.g. claustrophobia).

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-06-2012
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	25-04-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-08-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL39165.091.12