Chemotherapy and cognitive functioning in breast cancer patients and the effects on patients' quality of life and health care consuption

Published: 16-06-2008
Last updated: 11-05-2024

The primary aim of the study is to identify breast cancer patients who experience objective and/ or subjective cognitive dysfunction one year after chemotherapy and find determinants of this cognitive dysfunction on patients' quality of life...

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-OMON33665

Source
ToetsingOnline

Brief title
Effect of chemotherapy and cognition on breast cancer patients' QOL and HCC

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Breast Cancer, Breast Neoplasm

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W,collectebusfondsen

Intervention

Keyword: chemotherapy, cognitive functioning, health care consumption, quality of life

Outcome measures

Primary outcome

Primary study parameters: subjective cognitive dysfunction, objective cognitive

dysfunction

Outcome of the study: quality of life, health care consumption

Secondary outcome

N.A.

Study description

Background summary

It concerns a widely set up research at women with breast cancer treated with chemotherapy. Cognitive dysfunction as side effect of chemotherapy is a long lasting and underestimated problem.

Study objective

The primary aim of the study is to identify breast cancer patients who experience objective and/ or subjective cognitive dysfunction one year after chemotherapy and find determinants of this cognitive dysfunction on patients' quality of life and health care consumption.

Study design

We want to include at least 300 women in the study (breast cancer and benign) during a periosd of one year.
Women with a benign diagnosis will be included as comparison group.
Neuropsychological tests will be done three times (before chemotherapy, 3 and 12 months after chemotherapy); at the same moments questionnaires will be completed.
Patients with a benign diagnosis (only in the St. Elisabeth hospital, Tilburg)

get also neuropsychological tests and completed questionnaires after diagnosis and 3 and 12 months after diagnosis.

Study burden and risks

N.A.

Contacts

Public
Sint Elisabeth Ziekenhuis

Postbus 90153
5000 LE Tilburg
NL
Scientific
Sint Elisabeth Ziekenhuis

Postbus 90153
5000 LE Tilburg
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Women visiting the outpatieny clinics with a suspicion of breast cancer

Exclusion criteria

disease recurrence at baseline or metastases; history of neuropsychologic and/ or psychiatric signs or symptoms that lead to deviant neuropsychologic test results (e.g. dementia); the use of medication that may lead to deviant neuropsychological results; alcohol and drug addiction; poor expression in the dutch language

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-01-2009
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	16-06-2008
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	26-01-2010
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL21576.008.08