

Climb Every Mountain

Published: 12-03-2013

Last updated: 18-07-2024

To study prevalence and consequences of cognitive, psychological, social and functional decline in elderly breast cancer patients, in comparison to a population elderly without breast cancer.

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-OMON40351

Source

ToetsingOnline

Brief title

Climb

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym

Breast Cancer, Breast carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Stichting Alpe d'Huzes/KWF
kankerbestrijding

Intervention

Keyword: Breast Cancer, Cancer survivorship, Elderly, Functioning

Outcome measures

Primary outcome

Questionnaires about physical, cognitive, social and psychological functioning, quality of life and physical activity. Also, the Timed up and Go Test and the Mini Mental State Examination (MMSE) will be performed

Secondary outcome

Not applicable

Study description

Background summary

In developed countries, 40% of breast cancer patients is older than 65 years of age at diagnosis and this percentage is increasing . High age is predictive for comorbidity and decreased functioning. Therefore these factors might influence treatment decisions in elderly breast cancer patients.

In elderly patients, cancer occurs in a background of normal aging and comorbidity, thereby making this specific population heterogeneous in nature.

In younger patients breast cancer is associated with profound psychological complaints and a negative effect on quality of life. Elderly patients, on the other hand, have more indolent tumors and they are affected by the disease physically more than psychologically. Decline in physical functioning is associated with higher mortality, regardless of age. Therefore, new strategies to decrease the effect of breast cancer on physical decline and to improve overall and disease-specific survival are needed.

Despite the aforementioned differences between younger and older breast cancer patients, research on cancer survivorship in the elderly is sparse.

Study objective

To study prevalence and consequences of cognitive, psychological, social and functional decline in elderly breast cancer patients, in comparison to a population elderly without breast cancer.

Study design

Prospective, non-randomised observational study.

Study burden and risks

Patients will have to fill out 4 questionnaires in 2 years. These questionnaires take about 20-30 minutes. The Timed up and Go Test and the MMSE will take about 10-15 minutes.

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Breast Cancer stage 0-III

70 years or older

Being able to read in Dutch

Signed informed consent

Exclusion criteria

Recurrent breast cancer
Stage IV breast cancer
Severe dementia or psychiatric disease

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):	03-05-2013
Enrollment:	650
Type:	Actual

Ethics review

Approved WMO	
Date:	12-03-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO
Date: 02-04-2013
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 21-05-2013
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 17-07-2013
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 02-09-2013
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 13-11-2013
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 17-07-2014
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO

Date: 08-10-2014

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

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	NL43463.058.13