Change of body composition in breast cancer: All-in Assessment

Published: 14-12-2012
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON44105

Source
ToetsingOnline

Brief title
COBRA-study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Danone,Friesland Campina,KWF-kankerbestrijding & stichting Alpe d'HuZes & TI Food and Nutrition,TI Food and Nutrition

Intervention

Keyword: Adjuvant chemotherapy, Body composition, Breast cancer, Patient Perception

Outcome measures

Primary outcome

Study I focusses on possible determinants of changes in body composition and muscle strength. To assess changes in body composition, DEXA-scans will be made before start, shortly after and a half year after chemotherapy. Moreover, changes in muscle strength will be assessed by measuring hand-grip strength and knee-extensor strength.

Study II assesses what the perceptions are of women with breast cancer, of women without breast cancer and of health care workers on potential changes in dietary intake, physical activity and quality of life and on possible interventions to curb those changes. To this end interviews and focus groups will be organised

Secondary outcome

To assess if changes in body composition and abdominal fat distribution during chemotherapy are associated with body composition, fat distribution and energy balance before chemotherapy.

To identify lifestyle and/or physiological markers related to changes in body composition and fat distribution during chemotherapy

To assess differences in perceptions between premenopausal women (<40 year) with recently diagnosed breast cancer and premenopausal women without breast cancer and older women from both groups on changes in dietary intake, physical activity and quality of life

To assess perceptions between women from another culture living in the

Netherlands with recently diagnosed breast cancer and other women on dietary

intake, physical activity and quality of life

To assess perceptions of taste and smell between women with recently diagnosed

breast cancer and other women

Study description

Background summary

Yearly, more than 60% of the 13,000 Dutch women diagnosed with breast cancer will receive adjuvant chemotherapy (CT) of which weight gain can be an important side-effect. American studies suggest that this weight gain consists of increases in fat mass with loss or no change in muscle mass leading to sarcopenic obesity. Moreover, muscle strength may weaken, leading to dynapenic obesity. Changes in body composition and muscle strength affect quality of life and increase the risk of disease recurrence, cardiovascular disease and diabetes.
It is not clear whether changes are indeed treatment-related as only few studies compared changes during CT with changes *normally* occurring over time.

Study objective

The aims of this project are to:
1. Assess what percentage of breast cancer patients experience accelerated gain in fat mass, loss of muscle mass and muscle strength as induced during chemotherapy
2. Assess whether changes in energy intake, protein intake and physical activity are associated with accelerated changes in body composition and muscle strength
3. Assess perceptions of women with breast cancer, women without breast cancer and health care workers on why potential changes in dietary intake, physical activity and quality of life occur
4. Assess how taste and odour perception changes during chemotherapy.

In order to plan and design a future intervention to reduce the occurrence of changes in body composition, the study also aims to:
1. Identify subgroups of women especially susceptible for changes in body composition and muscle strength
2. Assess perceptions of women with breast cancer, women without breast

cancer and health care workers on possible interventions to curb changes in dietary intake, physical activity and quality of life

Study design

The COBRA-study consist of 2 parts with different study techniques. A quantitative part and a qualitative part.

the quantitative part is an observational study among breast cancer patients (n=300) and among a comparison group of women without breast cancer (n=300) matched on age (range, +/- 2years). There are four moments of measurement in this study. For women with breast cancer this moments are: before start of the chemotherapy (CT), during CT, at the end of CT (1-3 weeks after the last cycle) and 6 months after CT. For women without breast cancer these moments are: at baseline, 3 months, 6 months and after 1 year.

We ask women who participate in this study to fill-out different questionnaires about, lifestyle, food intake, physical activity, fatigue, depression and quality of life. In addition, blood samples will be drawn and we will perform different measurements. Participants are asked to underwent three times bio-impadance spectrometry and a DEXA-scan. Muscle strength will be assessed three times by hand grip strength, Sit-to-stand test and knee extensor strength. physical activity will be measured in two ways, with questionnaires and with accelerometers. The accelerometer has to be worn during a week at each moment of measurement. In addition, participants will complete four times a 24 hour recall about their food intake during a (telephone) interview.

Women in the comparison group (without breast cancer), will have the same questionnaires and measurements.

A sub group of 30 patients and 30 controls will be asked to participate in four extra measurements regarding taste and smell perception as well as food preference tests.

During the qualitative part of this study women with and without breast cancer will be interviewed four and two times, respectively followed by one or more focus groups. the number of interviews and focus groups is dependent on saturation. In addition, health care workers will be interviewed once, followed by one or more focus groups. Women from not-western culture with breast cancer will also be interviewed followed by one or more focus groups.

Participants for study 2 will mainly be sampled from the study population of study 1. This will enable combining parts of the results of the qualitative study with the measurements of the quantitative study (mixed methods approach).

This table shows the measurements taking place during each moment of measurement.

Before CT During CT At end of
CT 6 months after CT

Study I:
questionnaires 1 22
3 4
blood sample 1 2
3 4
body measurements 1
3 4
physical activity 1
2 3 4
24 h recall(tel) 22

Taste and smell test 1
2 3 4
Food preference test 1
2 3 4

Study II:
Interviews 1
2 3 4
Focus groups after the interviews

Study burden and risks

The burden for patients and women of the comparison group fluctuates over time and depends also on whether or not subjects participate in the subgroups or study 2. Upon recruitment patients and women in the comparison group have to fill out several questionnaires, donate a blood sample. Moreover DEXA-scans will be performed, muscle strength will be assessed. In addition, the subjects will be asked to wear an accelerometer (which will be sent to them by mail) for 7 consecutive days, During chemotherapy, (or at 3 months for the comparison group), subjects will be asked about dietary intake with telephone based 24h-recalls: to this end, a dietician will call the subjects and will collect information during an interview of maximal 30 minutes. Moreover, the subjects will be asked to wear an accelerometer again. Shortly after the end of chemotherapy and 6 months after the end of chemotherapy (or at 6 and 12 months for the comparison group)*, they will again be asked to fill out several questionnaires and to donate a blood sample. Moreover DEXA-scans will be performed and muscle strength will be assessed and the subjects will be asked to wear an accelerometer.

Women who participate in extra test sessions for taste and smell will be visited four time at their home. During these sessions they will complete

taste, smell and food preference tests.

Participants of study 2 will (predominantly) be selected from the study population of study 1. This will enable combining results of the qualitative study with measurements of the quantitative study. Participants of study 2 will be asked for an interview, which will take place at their home, and for focus groups, which will take place at a central place. Participants who take part in study 2 will not be asked for subgroups of study 1.

* from june 2016 onwards, the measurements of Dexa-scan and muscle strength are omitted for the comparison group.

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

Breast cancer patients aged 18 or older, with newly diagnosed, incident, non-advanced (I-IIIA,), operable breast cancer in one of the participating hospitals. scheduled for initiating 2nd or 3rd generation adjuvant chemotherapy, no history of cancer or treatment with chemotherapy.
Healthy women without breast cancer, who are similar to the patient group as far as age (range, +/- 2 years).

Exclusion criteria

A history of cancer or earlier treatment with chemotherapy, non-Dutch speaking, dementia or another mental condition that makes it impossible to fill out a questionnaire or answer 24hr recalls correctly or to participate in interviews and focus groups. An extra exclusion criteria for premenopausal women is a pregnancy or intention to get pregnant during participation in the study.

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-05-2013
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO Date:	14-12-2012
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	15-07-2013
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	20-08-2013
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	20-12-2013
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	06-03-2014
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	15-04-2014
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	09-09-2014
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	30-09-2014
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO Date:	01-10-2015
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)
Approved WMO	

Date:	23-08-2016
Application type:	Amendment
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL40666.081.12