Quality of life experience after neoadjuvant chemotherapy in HER2-positive breast cancer patients: a focus group study

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

Summary

ID

NL-OMON49288

Source
ToetsingOnline

Brief title
Focus group TRAIN-2: quality of life.

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, mamma carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

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

Intervention

Keyword: (health related) quality of life, breast cancer, HER-2 positive, neoadjuvant

Outcome measures

Primary outcome

health-related quality of life experience

Secondary outcome

not applicable

Study description

Background summary

Outcomes for stage II and III HER2-positive breast cancer patients improved drastically since the introduction of dual HER2-blockade. Therefor the number of HER2-positive breast cancer survivors previously treated with chemotherapy is increasing. Treatment with chemotherapy is known to influence quality of life, cognitive functioning, fine motor function, fatigue, depression, and sexual functioning.

Within the TRAIN-2 study patients were treated with two chemotherapy regimens with unknown specific influence on health-related quality of life.
Health-related quality of life was also not an endpoint within this phase II study. The regimens used in this trial are now widley used regimens. A qualitative study with focus groups will give us more insights in the differences in health-related quality of life within this population. The outcomes of the focus groups can also directly be used to adjust EORTC quesstionnaires for this specific group. We can used these to better measure health related quality of life in neoadjuvant treated breast cancer patients.
The outcomes of these studies can hopefully help to make considered treatment dicisions.

Study objective

The primary objective is to identify the relevant domains of health-related quality of life as experienced by patients who are previously treated with neoadjuvant chemotherapy for HER2-positive breast cancer.

Secondary Objectives:
* To adjust validated quality of life questionnaires (QLQ-30 & BR-45) according to the experience of previously treated HER2-positive breast cancer patients in order to create a fitting tool to measure health related quality of life during and after breast cancer treatment in a specific population.
* To validate the adjusted questionnaires.
* To evaluate quality of life experience in HER2-positive breast cancer survivors after neoadjuvant chemotherapy with and without anthracylines.

Study design

This is an qualitative study. Potential subjects who have previously been treated in the TRAIN-2 study will be asked to participate after permission of their treating physician. A minimum of three focus groups will be organized to identify domains of HRQoL after neoadjuvant treatment for HER2 positive breast cancer. Initially, three focus groups will be organized with 6-8 participants, which results in a sample size of 18 to 24 participants. Additional focus group sessions will be held until no new information is gained, and data saturation is reached (i.e., no new domains are retrieved).

Study burden and risks

The burden of participation is a maximum of 2,5 hour time investment and to fill in the QLQ-30 and BR-45 EORTC questionnaires during the meeting.

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

* Signed informed consent
* * 18 years
* Treated in the TRAIN-2 study for stage II or III HER2-positive breast cancer at the NKI
* Willing and being able to fill in a questionnaire
* Willing to speak about and discuss different domains of HRQoL
* Proficient in Dutch

Exclusion criteria

* Evidence of breast cancer recurrence / second primary cancer
* History of severe psychiatric illness or dementia

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending

Start date (anticipated):	01-12-2019
Enrollment:	24
Type:	Anticipated

Ethics review

Approved WMO Date:	20-02-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL72034.031.19