Importance of patient reported outcomes in choice of therapy for mamma patients

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The objective of the study is to assess which outcomes are most important to patients, so that we can inform them better and contribute to decision making. If patients, depending on treatment or age, consider PROMSs more or less important than...

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-OMON38173

Source
ToetsingOnline

Brief title
IMPACT-study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast therapeutic procedures

Synonym
Breastcancer, malignant tumor breast

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Stichting Zoleon

Intervention

Keyword: Breast cancer, Clinical outcomes, PROMs, Treatment

Outcome measures

Primary outcome

An overview of the more en less important outcomes after treatment of breast

cancer in the opinion of patients.

Secondary outcome

not applicable

Study description

Background summary

Currently the decision for a treatment for breast cancer is made by the doctor and the patient together. New breast cancer patients receive a lot of information. The information the doctor is giving is mainly about clinical outcomes and not so much about the patient reported outcome measurements (PROMs). Recently there is more interest to inform patients about PROMs, to let the patients know what the consequences are for their daily functioning.

Study objective

The objective of the study is to assess which outcomes are most important to patients, so that we can inform them better and contribute to decision making. If patients, depending on treatment or age, consider PROMSs more or less important than clinical outcomes, then the results of this project can helplp to adjust information based on this difference.

Study design

The study is a retrospective, internet-based questionnaire study (a single questionnair).
The questionnair consists of 3 parts:
I. 20 introductory questions, about age, family situation, their diagnosis, their treatment, etc.
II. 3 questions about the importance of the different outcomes in the opinion of the patient.

III. 12 conjoint tasks. In these conjoint tasks the respondents get repeatedly presented two virtual patients, they have to choose which of these two virtual patients got the best treatment in their opinion.

Study burden and risks

There are no risks for the participants.
They will fill in a questionnaire on the internet, taking about 30 minutes.

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

- 18 years or older

- Underwent surgery for breastcancer between 9 and 18 months ago

Exclusion criteria

- Metastatic disease

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2013
Enrollment:	650
Type:	Actual

Ethics review

Approved WMO Date:	11-12-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	18-12-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL46771.058.13