

A study of Outcome, Quality of Life and Satisfaction in women after breast reconstruction.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22225

Source

NTR

Health condition

Breast cancer, (preventive) mastectomy, BRCA gene mutation, Breast reconstruction, autologous reconstruction, alloplastic reconstruction.
Borstreconstructie, (preventieve) ablatie, , BRCA gen mutatie, autologe reconstructie, alloplastische reconstructie

Sponsors and support

Primary sponsor: Univerity Medical Centre Groningen

Source(s) of monetary or material Support: sponsor

Intervention

Outcome measures

Primary outcome

The primary outcome measure is the Quality of Life as measured with the Breast Q.

Secondary outcome

1. Health related Quality of Life as measured by the Rand 36;
2. The fear for recurrence of cancer on the QoL of the breast cancer patients as measured by the CARS;
3. Anxiety and Depression as measured by the HADS;
4. Cosmetic outcome as measured by the Strasser Score and the POSAS.

Study description

Background summary

Objective:

To systematically research the experiences concerning psychosocial impact and quality of life and their medical outcome of women who undergo different types of reconstruction. The results of this study may help to improve our insight into the effects of our work. With this knowledge we expect to be able to further improve the care for those patients. More specifically, this research aims to provide women who consider breast reconstruction with better counselling and help women make the best decision for an optimal treatment.

Study objective

We expect that from 6 weeks on after a breast reconstruction with autologous material, quality of life is higher than after reconstruction with implants.

Study design

The participants will fill in QoL questionnaires pre-operative and then at 6 weeks, 6 months, 1 year and 3 years post reconstruction.

Intervention

For this study the main source for data are patient reported data, resulting from questionnaires.

Contacts

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Eligibility criteria

Inclusion criteria

1. Women who have/had breast cancer and need(ed) a mastectomy and will undergo a breast reconstruction;
2. Women with BRCA gene mutation, who undergo a preventive mastectomy and want their breasts primarily reconstructed;
3. Young women with breast cancer who need preventive mastectomy of the other breast and want their breast reconstructed;
4. Informed consent.

Exclusion criteria

1. Women who do not understand the Dutch language well;
2. Women who are illiterate in reading and/or writing;
3. Women below 18 years of age;
4. Women who are legally incompetent;
5. Women who have a bad prognosis. (terminally ill, patients with metastases);

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-08-2012
Enrollment:	116
Type:	Anticipated

Ethics review

Positive opinion	
Date:	18-07-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38410
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3392
NTR-old	NTR3534
CCMO	NL32863.042.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38410

Study results

Summary results

N/A