

# A retrospective study of outcome, quality of life and satisfaction in women after breast reconstruction

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON34202

### Source

ToetsingOnline

### Brief title

A retrospective study on QoL in breast reconstruction

### Condition

- Other condition

### Synonym

breast reconstruction, mamma reconstruction

### Health condition

health related quality of life

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

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

## Intervention

**Keyword:** breast reconstruction, mastectomy, quality of life

## Outcome measures

### Primary outcome

By using quality of life questionnaires we can score the satisfaction, quality of life and body image of patients who underwent a mastectomy with breast reconstruction. This can be combined with objective physical and medical variables. Pre- and postoperative photos will be scored by a panel of experts and a lay person.

### Secondary outcome

N/A

## Study description

### Background summary

Between September 2006 and July 2010 the Plastic Surgery Department has performed breast reconstructions on around 140 women with different techniques. All techniques used are of high medical standard. Although we do have some impressions as to what impact the women experienced concerning their quality of life, this is not based on rigorous research. It is not clear to what extent which technique gives the highest quality of life.

In the literature there are sufficient articles about the medical side of breast reconstruction but a paucity of high quality research on the quality of life outcome of breast reconstruction. This proposal concerns a retrospective cohort study that aims at understanding the outcome, quality of life and satisfaction of women undergoing breast reconstruction. A cohort of women who chose not to have a breast reconstruction is used as a reference group.

## Study objective

The objective of this study is to find answers to the question whether breast reconstruction after (preventive) mastectomy improves quality of life and which breast reconstruction technique gives the highest quality of life for these women. Researching the outcome, psychosocial and quality of life impacts on women who undergo breast reconstruction will enable us to further tailor the reconstruction according to the patients needs and to give the best possible counselling, treatment and care.

## Study design

A retrospective cohort study has been designed whereby 3 cohorts are studied: patients who undergo only a mastectomy, patients who have a mastectomy and an autologous reconstruction and patients who have a mastectomy and breast implants. These cohorts of patients have received treatment at the Division for Surgical Oncology (Dept of Surgery) and/or the Dept of Plastic Surgery

## Study burden and risks

It is unlikely that the patient will benefit personally from the results of the study.

The expectation is that once the objectives of the study have been achieved, the department can optimize the treatment, counselling and care for future patients.

Answering the questionnaires could be a confrontational experience. This will be explained in the patient information letter and the patient will get the opportunity to consider this aspect of the study. Of course the patient can always withdraw from the study.

## Contacts

### Public

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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

women who had a mastectomy only and women who had mastectomy plus breast reconstruction

### Exclusion criteria

Patients with a poor prognosis

## 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):	22-10-2010
Enrollment:	135
Type:	Actual

## Ethics review

Approved WMO	
Date:	14-10-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

## 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	NL33057.042.10