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

Published: 14-10-2010
Last updated: 03-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	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 wit 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 satisfacton 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 tot the patients needs and to give the best possible counselling, treatment and care.

Study design

A rretrospective 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 personnaly from the results of the study.
The expectation is that once the objectives of the study have been achieved, the department can optimalize the treatment, counselling and care for future patients.
Answering the questionnairs could be a confrontational experience. This wil be explained in thepatient information letter and the patient will get the opportunity to consider this aspect of the study. Ofcourse the patient can always withdraw from the study.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen
NL

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