Nipple sensitivity after prophylactic nipple-sparing mastectomy compared to healthy BRCA1/2 gene mutation carriers.

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The aim of this study is to objectify nipple-areola complex sensitivity in women who underwent unilateral or bilateral prophylactic NSM in Erasmus MC-Daniel den Hoed Cancer Center and their satisfaction with this operation, compared to healthy women...

Ethical review	Approved WMO
Status	Pending
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Observational non invasive

Summary

ID

NL-OMON37622

Source
ToetsingOnline

Brief title
NISPRO

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Breast therapeutic procedures

Synonym
breast amputation sparing the nipple, nipple sparing mastectomy

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Pink Ribbon

(onderzoekerssalaris)

Intervention

Keyword: BRCA1/BRCA2, nipple sparing mastectomy, satisfaction, sensitivity

Outcome measures

Primary outcome

Nipple sensitivity, mean scores per nipple.

Results of the questionnaire: body image, satisfaction with the operation.

Secondary outcome

Co-morbidity: diabetes mellitus, BMI

Smoking status

Post-operative complications: wound infection, necrosis of the nipple,

re-operation

Study description

Background summary

Many women with a BRCA1/2 mutation choose to undergo (bilateral) prophylactic mastectomy, diminishing breast cancer risk by by 90-100%. Lately there has been increasing interest for the cosmetic results after such an operation. To allow for immediate breast reconstruction after prophylactic mastectomy, a subcutaneous mastectomy is performed to spare the skin envelope of the breast. It is possible to spare the nipple together with the skin. Long-term safety and cosmetic results of nipple-sparing mastectomies are unknown. However, some women choose nipple sparing mastectomy because of the presumed more natural result of this operation.

Study objective

The aim of this study is to objectify nipple-areola complex sensitivity in women who underwent unilateral or bilateral prophylactic NSM in Erasmus MC-Daniel den Hoed Cancer Center and their satisfaction with this operation,

compared to healthy women who never underwent a breast operation.

Study design

Women who underwent uni- or bilateral prophylactic nipple-sparing mastectomy are asked to participate at least one year after operation.
After obtaining informed consent, sensitivity of the NAC will be tested using Semmes-Weinstein monofilaments with five increasing diameters. Starting with the smallest monofilament diameter three short touches are applied to five different sites of the nipple, and to four sites para-areolar lateral and medial. If the patient doesn*t respond, monofilament diameters are increased step by step, until touch is distinguished.
The diameter of the lightest monofilament which can be distinguished is scored. The mean of all scores is calculated,

Each site will be tested for hot and cold sensations using metal probes at approximately 10°C and 40°C. If the patient is able to distinguish both temperatures, she will score 1 point per site.

Additionally, patients are asked to fill out two questionnaire, Hopwood's Body Image Scale (BIS) and the Dutch Breast-Q (reconstruction module). The 10-point BIS contains questions about about body image and validation of a Dutch version is about to be finished. Thirteen complementary questions about nipple sensitivity and satisfaction with the choice of operation are added. The BIS and the additional questions are only administered to the operated arm.
The Breast-Q reconstruction module contains questions concerning body image, satisfaction with the operation and cosmetic results and consists of a pre-operative and a post-operative part. The pre-operative questions will be administered to the control arm, the post-operative questions will be administered to the group that underwent a nipple-sparing mastectomy.

Study burden and risks

The study burden is very low. No invasive interventions are done and the unique outpatient clinic visit takes only about 15 minutes.
Some questions in the questionnaire concern private matters.
There are no risks for the tested subjects.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Groene Hilledijk 301

Rotterdam 3075 EA
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Groene Hilledijk 301
Rotterdam 3075 EA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

BRCA1/BRCA2 gene mutation carriers who underwent a prophylactic nipple sparing mastectomy, at least one year after operation.

Exclusion criteria

history of breast cancer

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:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2012
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Date:	05-09-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL40189.078.12