Bilateral PROphylactic mastectomy; Should we preserve the pectoral FAScia? - PROFAS 1

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22340

Source
Nationaal Trial Register

Brief title
PROFAS 1

Health condition

Female BRCA 1 or 2 gene mutation carries, bilateral prophylactic mastectmy, pectoral fascia preservation, seroma production

Sponsors and support

Primary sponsor: Erasmus MC Cancer Insitute, Dpt. of Surgical Oncology
Source(s) of monetary or material Support: N/a

Intervention

Outcome measures

Primary outcome

To evaluate to feasibility of a full-scale study.

Secondary outcome

Impact of removal versus preservation of the pectoral fascia on seroma formation. Seroma is defined as any clinically detected collection of fluid requiring aspiration. The drain production and the number of days the drain will be left in situ will be measured. The volume of 30 ml in 24 hours is established as a guideline for timing of drain removal.

Impact of removal versus preservation of the pectoral fascia on postoperative pain, wound related issues as hematoma and infection, and hospitalization duration.

Study description

Background summary

Rationale: Many surgical guidelines promote the removal of the pectoral fascia in (modified radical) mastectomies for invasive breast cancer, but there is no evidence to support this statement in (bilateral) prophylactic mastectomies. On the other hand, the preservation of pectoral fascia may be of great help in reconstructive surgery, since it aids the medial and inferior aspects of the pectoralis muscle to remain firmly attached to the thoracic wall, greatly reducing the risk of its accidental detachment, which may jeopardize implant coverage. And in the same way, it helps with the cohesions of the pectoralis fibres, preventing its disruption during dissection.

Reported wound related local complications following modified radical mastectomy include seroma, flap necrosis, infection, hematoma and nerve injury. Seroma causes discomfort and may delay the reconstructive procedures. Whether the removal or preservation of the pectoral fascia influences seroma formation following modified radical mastectomy remains unclear to our knowledge. Our hypothesis is that preservation of the pectoral fascia may lead to a decreased seroma formation when compared to fascia removal, and has a beneficial effect on breast reconstructive surgery.

Objective: To assess the feasibility of a full-scale study and on the impact of removal versus preservation of the pectoral fascia on seroma formation in women operated with bilateral prophylactic mastectomy.

Study design: A double blinded, prospective, randomized controlled pilot-study with a within-subject design.

Study population: Woman > 18 years, presenting in the Academic Breast Cancer Center Rotterdam, who are opting for bilateral prophylactic mastectomy are eligible for the study.

Intervention (if applicable): Randomization will occur within the patient, with each breast randomized between preservation and removal of the pectoral fascia.

Main study parameters/endpoints: The main study parameter is the feasibility of the study.

Secondary endpoints: Impact of removal versus preservation of the pectoral fascia on seroma formation. Seroma is defined as any clinically detected collection of fluid requiring aspiration. The drain production and the number of days the drain will be left in situ will be measured. The volume of 30 ml in 24 hours is established as a guideline for timing of drain removal. Impact of removal versus preservation of the pectoral fascia on postoperative pain, wound related issues as hematoma and infection, and hospitalization duration.

Study objective

Our hypothesis is that preservation of the pectoral fascia may lead to a decreased seroma formation when compared to fascia removal, and has a beneficial effect on breast reconstructive surgery.

Study design

Preoperative informed consent and randomisation
The investigational part of the operation is preservation of the pectoral fascia. Since the within-subject randomization design of the trial preservation of the pectoral fascia will be performed in one breast (intervention), while removal of the pectoral fascia will be performed in the contralateral breast of the same patient (control). Further medical care (treatment and after-care) and the related nursing and follow-up care will be performed according the standard care protocol.

Intervention

A double blinded, prospective, randomized controlled pilot-study with a within-subject design, will be performed. Patients will be asked to participate at the outpatient clinic of the Erasmus MC, Cancer Institute. Bilateral prophylactic mastectomies will be performed in the Erasmus MC.

Randomization will occur between breasts within the patient. One of the breasts will be the intervention which contains the preservation of the pectoral fascia versus the other breast,

which will be the control with conventional surgery and thereby removal of the pectoral fascia. Patients will be blinded for randomization.

Contacts

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Eligibility criteria

Inclusion criteria

Woman > 18 years, presenting in the Academic Breast Cancer Center Rotterdam, who are opting for bilateral prophylactic mastectomy are eligible for the study.

Exclusion criteria

Diagnosis of breast cancer

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2018
Enrollment:	20
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL7404
NTR-old	NTR7620

Register	ID
CCMO	NL67929.078.18

Study results