Bilateral prophylactic mastectomy; Should we preserve the pectoral fascia?

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To assess a pilot-study on the impact of removal versus preservation of the pectoral fascia on total drain volume, time to drain removal and needle aspirations (and thus seroma) in women undergoing bilateral prophylactic mastectomy.

Ethical review	Approved WMO
Status	Pending
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON49867

Source
ToetsingOnline

Brief title
PROFAS

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast therapeutic procedures

Synonym
BRCA mutation carriers

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

Intervention

Keyword: Bilateral prophylactic mastectomy, Pectoral fascia preservation

Outcome measures

Primary outcome

Impact of removal versus preservation of the pectoral fascia on seroma formation. 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. Seroma is defined as any clinically detected collection of fluid requiring aspiration.The number of needle aspirations and volume in ml will be reported.

Secondary outcome

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

Study description

Background summary

Many surgical guidelines recommend the removal of the fascia to ensure radicality. However, there is no evidence to support this statement in early operable breast cancer, and certainly not in prophylactic mastectomies. A thorough research on literature shows numerous citations to the fact that the fascia should be removed, but no explanation whatsoever to why this should be done.
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 post-operative seroma formation and thus drainpolicy (e.g. total drain volume, time to removal) following mastectomy remains unclear. Our hypothesis is that

preservation of the pectoral fascia may lead to a decreased total drain volume, time to drain removal and needle aspirations (and thus seroma formation) when compared to fascia removal.

Study objective

To assess a pilot-study on the impact of removal versus preservation of the pectoral fascia on total drain volume, time to drain removal and needle aspirations (and thus seroma) in women undergoing bilateral prophylactic mastectomy.

Study design

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

Intervention

All patients will undergo a bilateral prophylactic mastectomy. Randomization will occur within the patient, with each breast randomized between preservation and removal of the pectoral fascia

Study burden and risks

No extra risks are associated to participation in the study, since the procedure was declared safe. Additional recorded variables will be monitored by the research team (i.e. nurses, breast surgeons, researcher), including hospital stay, the duration of drain use, the total drain volume, and if applicable wound related issues as hematoma and infection, the total volume of aspirated seroma fluid and the number of needle aspirations (after drain removal). In conclusion, with exception of preservation of the pectoral fascia (in one breast) all the procedures will be performed according to the standard protocol for bilateral prophylactic mastectomy as defined by the Erasmus MC Cancer Institute

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Female and age 18 years or older
- Scheduled for bilateral prophylactic mastectomy

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

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	21
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-12-2020
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	NL72939.078.20