

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

Gepubliceerd: 07-11-2018 Laatste bijgewerkt: 18-08-2022

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.

<b>Ethische beoordeling</b>	Niet van toepassing
<b>Status</b>	Werving nog niet gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON22340

### Bron

Nationaal Trial Register

### Verkorte titel

PROFAS 1

### Aandoening

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

## Ondersteuning

**Primaire sponsor:** Erasmus MC Cancer Institute, Dpt. of Surgical Oncology

**Overige ondersteuning:** N/a

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

To evaluate to feasibility of a full-scale study.

## Toelichting onderzoek

### Achtergrond van het onderzoek

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.

## **Doel van het onderzoek**

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.

## **Onderzoeksopzet**

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.

## **Onderzoeksproduct en/of interventie**

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.

## **Contactpersonen**

## **Publiek**

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## **Wetenschappelijk**

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## **Deelname eisen**

### **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

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

### **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

Diagnosis of breast cancer

## **Onderzoeksopzet**

## Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

## Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2018
Aantal proefpersonen:	20
Type:	Verwachte startdatum

## Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

Register	ID
NTR-new	NL7404
NTR-old	NTR7620

**Register**

CCMO

**ID**

NL67929.078.18

## Resultaten