

# Radicality of (simple) mastectomy: residual breast tissue

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Riskreduction of developing breast carcinoma by means of better surgical techniques (removing all normal breast tissue).

**Ethical review**

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**Status**

Recruitment stopped

**Health condition type**

Chromosomal abnormalities, gene alterations and gene variants

**Study type**

Interventional

## Summary

### ID

NL-OMON33691

### Source

ToetsingOnline

### Brief title

Radicality mastectomy

### Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Breast neoplasms malignant and unspecified (incl nipple)
- Breast therapeutic procedures

### Synonym

breast cancer, carcinoma mammae

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Medisch Centrum Leeuwarden

**Source(s) of monetary or material Support:** MCL wetenschapscommissie in samenwerking met het IKNO

## Intervention

**Keyword:** ablatio mammae, breast cancer, radical

## Outcome measures

### Primary outcome

< 10% positive samples (glandular tissue in resectionmargin) by 60-70% of the patients in the intervention group.

### Secondary outcome

- Percentage patients with positive sample(s).
- Location of residual breast tissue
- Risk factors:
- Age
- Menopause
- BMI
- Weight & Volume breast
- Skin-sparing mastectomy vs. simple- & radical mastectomy
- Resection surface

## Study description

### Background summary

After a mastectomy for breast cancer there is a realistic chance of developing a local recurrence. It can be either a metastasis of the primary tumor or a second primary tumor which has developed in the remaining breast tissue. The finding of normal breast tissue around the recurrence and the development of breast cancer after a prophylactic mastectomy support this view. So far little is known about residual breast tissue after a mastectomy.

### Study objective

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Risk reduction of developing breast carcinoma by means of better surgical techniques (removing all normal breast tissue).

## **Study design**

Multiple sections will be taken from the periphery (breast preparation) to detect areas where glandular tissues might extend to the resection margins. Informing the surgeons about the regions of predilection for leaving breast tissue behind and analysing the percentages of glandular tissue in the periphery in the control groups vs the intervention group (Kruskal-Wallis test & Chi2 test).

## **Intervention**

The intervention consists of informing the surgeons about the regions of predilection for leaving breast tissue behind.

## **Study burden and risks**

No risks.

## **Contacts**

### **Public**

Medisch Centrum Leeuwarden

Postbus 888  
8901 BR Leeuwarden  
Nederland

### **Scientific**

Medisch Centrum Leeuwarden

Postbus 888  
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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Simple or radical mastectomy for malignancy, benign disorders or prophylactic.

### Exclusion criteria

Male

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2008
Enrollment:	350
Type:	Actual

## Ethics review

Approved WMO  
Date: 22-05-2008  
Application type: Amendment  
Review commission: RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

## 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	NL21801.099.08