

Radicality of (simple) mastectomy: residual breast tissue

Published: 01-07-2008

Last updated: 10-08-2024

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

Ethical review	-
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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Riskreduction 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

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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