The impact of reconstructive breast surgery on the risk of developing lymphedema

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast disorders
Study type	Observational non invasive

Summary

ID

NL-OMON38329

Source
ToetsingOnline

Brief title
PAL 2

Condition

- Breast disorders
- Breast therapeutic procedures
- Lymphatic vessel disorders

Synonym
arm swelling, lymphatic dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Breast cancer, Breast reconstruction, Lymphedema

Outcome measures

Primary outcome

The main endpoints are objective lymphedema (water displacement volume difference > 200 ml) and subjective lymphedema (swelling and heaviness of the treated limb perceived by patient).

Secondary outcome

In the descriptive part of this study we will look at the 1) presence and severity of lymphedema and the correlation with risk factors, 2) functional consequences due to lymphedema and 3) lymphedema staging

Study description

Background summary

Breast reconstructive surgery has over the years become an important addition to the management of breast cancer in women. Little is known about the effect breast reconstruction has on the development of lymphedema: a possible additive risk increase or even a risk decrease. Lymphedema is a highly debilitating complication that among others causes pain, reduced range of motion and emotional stress. Given the fact that women under the age of 65 represent the majority of patients undergoing reconstruction and with focus on the quality of survivorship, research is relevant.

Study objective

Our primary objective is to determine the effect of breast reconstruction on the risk of developing lymphedema. Secondarily, we will look at lymphedema and the correlation with 1) primary and secondary breast reconstruction, 2) the extent of axillary dissection, 3) adjuvant therapy, 4) risk factors, and 5)

functional consequences.

Study design

This study is a cross-sectional study, a partnership of the general and plastic surgery department. Together we will form a cohort of women with the aim of determining the impact of breast reconstruction on the development of lymphedema.

Study burden and risks

The patients are not subject to any risks or complications during the course of this study, therefore insurance exemption is requested. The women will visit one of the participating institutes for a one time medical examination and interview of approximately 1 hour. During this examination, the upper limbs will be assessed for sensory, motor, strength and mobility changes. Furthermore, we will measure the volume and circumference difference between the treated and untreated side using two measuring techniques. One questionnaire about *risk factors for lymphedema* is to be filled in.

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

1) Female 2) Mastectomy with or without breast reconstruction (primary or secondary and by means of prosthesis or autologous tissue) 3)Operated on between January 1st 2006 and December 31st 2010. 4) unilateral disease and oncological operation.

Exclusion criteria

1) Bilateral breast disease or oncological operation 2) Refused informed consent 3) Death 4) Relapsed cancer at time of study inclusion 5)Metastatic disease

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-11-2011
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	19-10-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-01-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	13-03-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	08-06-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	18-12-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL37212.068.11