

Comparison of Postoperative Breast Sensation between Different Flap Types for Innervated Autologous Breast Reconstruction

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational non invasive

Summary

ID

NL-OMON53383

Source

ToetsingOnline

Brief title

Comparison of Breast Sensation between Different Flap Types

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym

breast sensation, loss of sensation

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: autologous breast reconstruction, breast cancer, breast sensation, quality of life

Outcome measures

Primary outcome

To compare breast sensation in different types of autologous breast reconstruction with sensory nerve coaptation.

Secondary outcome

To compare the patient reported quality of life in different types of autologous breast reconstruction with sensory nerve coaptation..

Study description

Background summary

Breast cancer is the most common cancer worldwide. Over the last decades, the focus of reconstruction after breast cancer has primarily been on aesthetics, but is shifting more and more towards other aspects of the reconstruction as well, such as breast sensation. Increase in postoperative breast sensation, which is known to increase quality of life, can be established by adding nerve coaptation to autologous reconstruction. Various studies regarding innervated reconstructions and breast sensation have been published, but often focus on one or two types of flaps. In this study, we will therefore compare sensation between different types of autologous breast sensation.

Study objective

Primarily, we will evaluate and compare postoperative sensation between different sensate autologous breast reconstructions. Secondly, we will evaluate and compare quality of life measured by the validated BREAST-Q questionnaire between the different reconstructions.

Study design

A cross-sectional, explorative study performed in the Maastricht University

Medical Centre (MUMC+). Breast sensation will be measured with three modalities: the Semmes-Weinstein monofilaments (SWM), the pressure specified sensory device (PSSD), and the quantitative sensory testing (QST). We will correct for several covariates with the statistical analysis, among which is postoperative time.

Study burden and risks

Participation is voluntarily. Participants can withdraw at any time during the study without further consequences. The measurement will take place at the outpatient clinic and duration will be approximately 60-90 minutes. The methods do not harm the participant and are not painful. There are no risks or complications associated or reported with these measurement techniques.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

- Female sex
- 18 years or older
- A history of breast cancer or carrier of BRCA1/2 gene mutations
- Underwent autologous breast reconstruction with a free flap (unilateral/bilateral, immediate/delayed)
- >7 months after reconstruction
- Sensory nerve coaptation
- Being mentally competent to be able to give informed consent.

Exclusion criteria

- Postoperative radiotherapy
- Known (neurological) conditions that affect the sensation such as diabetes mellitus and neuropathy, regardless of cause

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 29-10-2024

Enrollment: 100

Type: Actual

Ethics review

Approved WMO

Date: 25-08-2023
Application type: First submission
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	NL83649.068.23