The Effect of Sensory Nerve Coaptation in DIEP Flap Breast Reconstruction on the Quality of Life: A Double-Blind Randomized Controlled Trial

Published: 29-11-2018
Last updated: 19-04-2025

The primary objective of this randomized controlled trial is to evaluate the effectiveness of sensory nerve coaptation in autologous breast reconstructions on the sensibility of the reconstructed breast, compared to spontaneous sensory recovery, and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON52616

Source
ToetsingOnline

Brief title
the DBR-NERVES trial

Condition

- Breast therapeutic procedures

Synonym
Insensate breast; numbed breast

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Kankeronderzoeksfonds Limburg (KOFL);grandnumber 30943443N

Intervention

Keyword: Breast Reconstruction, Microsurgical Nerve Coaptation, Quality of Life, Sensory Recovery

Outcome measures

Primary outcome

The primary outcome measure will be quality of life, which will be evaluated using the BREAST-Q questionnaire (Reconstruction module). This is a validated questionnaire that is specifically designed for breast cancer patiënts undergoing breast reconstruction. Participants will be asked to complete the questionnaires pre-operatively and at 6, 12 and 24 months follow-up (optionally additional follow-up at 36 and 60 months). The score of the BREAST-Q will be evaluated using the Q-score program. The higher the BREAST-Q score, the higher the patient reported quality of life.

Secondary outcome

The secondary outcome will be sensation of the breast. Sensation will be tested using Semmes-Weinstein monofilaments (SWM), Pressure-Specified Sensory Device (PSSD) and/or Quantitative Sensory Testing (QST). Examinations will be performed at inclusion, 3, 6, 12, 18 and 24 months follow-up (optionally additional follow-up at 36 and 60 months).

Study description

Background summary

Breast cancer has become the most common cancer among women worldwide. Besides women receiving treatment for breast cancer, women genetically at risk because of BRCA1/2 mutations often undergo prophylactic mastectomy. Therefore, more women have to live with the consequences of (prophylactic) breast cancer treatment. In addition, the time after treatment continues to prolong since women are younger when receiving therapy. Consequently, the quality of life after (prophylactic) breast cancer treatment is becoming of fundamental importance. Restoring the body to as normal as possible, after a mastectomy has proven to increase quality of life. In terms of aesthetics, exceptional, natural looking results can already be achieved by autologous breast reconstruction. However, previous research shows that the question *does your reconstructed breast feel like your own?*, is one of the most important determinants in patient satisfaction. An innovative technique; sensory nerve coaptation might restore the sensation of the reconstructed breast which could significantly improve the quality of life of breast cancer patients according to the first pilot study.

Study objective

The primary objective of this randomized controlled trial is to evaluate the effectiveness of sensory nerve coaptation in autologous breast reconstructions on the sensibility of the reconstructed breast, compared to spontaneous sensory recovery, and how this influences the quality of life of breast cancer patients.

Study design

A double-blind single-center, randomized controlled trial (RCT), conducted in Maastricht University Medical Center (Maastricht UMC+). Patients will be randomised into one of two study groups: group 1 will receive a standard DIEP flap breast reconstruction (without sensory nerve coaptation), group 2 will receive a DIEP flap breast reconstruction with sensory nerve coaptation.

Intervention

The sensory nerve coaptation will be an additional technique used in DIEP flap breast reconstructions. In DIEP flap breast reconstruction the artery and vein supplying the transplanted tissue are anastomosed to an artery and vein on the thorax, mostly the internal mammary vessels. Technically, it is possible to coapt a sensible nerve of the transplanted tissue to one of the thorax to facilitate nerve regeneration of the reconstructed breast5. This will approximately extend the operating time with 20 minutes and does not entail any extra specific risks for the patient.

Study burden and risks

Participation is voluntarily. Participants can withdraw at any time during the study without further consequences. Patients will be randomised into one of two groups: they either will receive a sensory nerve coaptation during the DIEP flap breast reconstruction, or they won*t. The last group, without a nerve anastomosis, will therefore receive a normal DIEP flap breast reconstruction, which is nowadays standard care for breast cancer patients. The operation time is prolonged with approximately 20 minutes. Patients who undergo DIEP flap breast reconstruction with sensory nerve coaptation are not more at risk because of the prolonged operation time. The follow-up and aftercare will be the same for both groups, protocolized for autologous breast reconstructions. The BREAST-Q questionnaire will be completed before operation and at 6, 12 and 24 months post-operatively. Completing the BREAST-Q questionnaire will approximately take 5 to 10 minutes each time. There are no risks or complications associated.
The sensory measurements will be done before operation and at 3, 6, 12, 18 and 24 months post-operatively at special follow-up moments in the study. The measurements will take place at the outpatient clinic and duration will be approximately 45 minutes each time the participant is measured. The sensory measurements will be done using SWM, PSSD and QST. These methods do not harm the participant and are not painful . There are no risks or complications associated or reported with these measurement techniques.
At the end of the individual follow-up period, at 24 months, all patients will be asked by one of the researchers whether or not they would like to remain blinded to the nerve coaptation and participate in a lengthened follow-up. Patients who approve will have a longer study follow-up with two extra measurement moments for breast sensation and quality of life: at 36 postoperative months (3 years) and at 60 postoperative months (5 years). The researchers will also remain blinded.
Patients who would like to be unblinded will be asked whether they think they have a nerve coaptation yes or no. Immediately afterwards they the result will be handed out to the patient.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25

Maastricht 6229 HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Women of 18 years or older
- Diagnosed with breast cancer of carriership of gene mutations related with breast cancer
- Undergoing unilateral or bilateral breast reconstruction via DIEP flap
- Immediate or delayed breast reconstruction

Exclusion criteria

- Known (neurological) conditions that affect the sensation such as diabetes mellitus or neuropathy (regardless of cause)
- Smoking
- BMI >35 kg/m2

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-07-2019
Enrollment:	118
Type:	Actual

Ethics review

Approved WMO Date:	29-11-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-01-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-10-2022
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

ID: 24157
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL67335.068.18