External Vacuum Expansion: evaluation in breast reconstructive surgery

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

Summary

ID

NL-OMON52848

Source
ToetsingOnline

Brief title
EVE

Condition

- Breast therapeutic procedures

Synonym
breast reconstruction, breast reconstructive surgery

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Zorginstituut Nederland & ZonMw

Intervention

Keyword: Autologous fat transfer, Breast reconstruction, Lipofilling, Vacuum Expansion

Outcome measures

Primary outcome

All women will have an MRI for Baseline Breast Volume measurement at the time of enrollment. Final breast volume will be also determined by MRI 12 months after the first grafting procedure (AFT#1).

The primary effectiveness endpoint is the Percentage Augmentation of the mastectomy defect at 12 months after AFT#1.

Secondary outcome

- The quality of the reconstructed breast tissue as determined by MRI. (Presence of necrotic cysts, their size and number)

- The patient reported satisfaction at baseline and post-AFT using the Breast-Q Questionnaire

- Return of sensation to the breast as determined by Semmes-Weinstein monofilaments (map of the reconstructed breast mound with record of sensory levels)

- Visual/standard photographic appearance of the reconstructed breast

- Difference in chest circumference between the peak of the reconstructed breast mound and the circumference just below the inframammary line

- Difference in bra cup size

- Difference in Breast Volume Increase from the randomization baseline after the three sessions of fat grafting (Final Reconstructed Breast Volumes) as measured by the validated Vectra 3D imaging system and the MRI.

Study description

Background summary

Breast cancer is the most common malignancy in females. After breast cancer, many patients suffer from anxiety to depression. Therefore, progressively more patients choose to have a breast reconstructed to increase her quality of life. The Breast-trial and the Breast-II study the effectiveness of autologous fat transfer (AFT) as a full breast reconstruction method. In these studies, the AFT treatment is combined with the use of external vacuüm expansion (EVE). The added value of the EVE has not been investigated yet and studies treating AFT for total breast reconstruction without the use of the EVE have been published worldwide. Because the use of the EVE is experienced as a burden by patients, e.g. time straining, skin irritations, pain and sleepless nights, clinical evidence on the efficacy of the EVE in combination with AFT is necessary.

Study objective

The primary effectiveness objective of this study is to determine whether breast reconstruction with fat grafting is more successful with the EVEBRA Device than a breast reconstruction with fat grafting without the EVEBRA.
The primary safety objective is to record adverse events during the course of the study and assess the safety of the EVEBRA Device in women undergoing post-mastectomy breast reconstruction with AFT.
This study also aims to determine the effectiveness of a new breast reconstruction technique: Autologous fat transfer (AFT). This technique combines the advantages of using the patients* own tissue (fat cells), while being minimally invasive compared to available techniques. So far, the research studying this technique does not provide high quality evidence on efficacy and safety, inhibiting the use of AFT in everyday practice.

Study design

The study is designed as a prospective, multicenter randomized, controlled, trial (RCT) of 90 post-mastectomy subjects at 5 sites. in the Netherlands. The study will employ a 2:1 randomization of patients receiving EVEBRA +AFT (treatment group) and patients not receiving EVEBRA, only AFT (control group).

Intervention

EVEBRA group: Subjects randomized into the EVEBRA group will receive the EVEBRA Device.
Control group: The control subjects will receive a conventional AFT breast reconstruction, without the use of the EVEBRA.

Both groups will receive a breast reconstruction using AFT.

Study burden and risks

To date, no studies have been performed to investigate the added value of the EVE when used in combination with AFT for total breast reconstruction. In contrast, reconstructive surgeons worldwide have published positive results of AFT procedures without the use of the EVE. AFT for total breast reconstruction is considered effective and safe. Additionally, The EVE device is experienced by a burden by patients because of its time straining features, skin irritations, insomnia and social consequences. This randomized control trial will provide more information on the effectiveness of the EVEBRA in combination with autologous fat transfer, without compromising the safety of the patients not receiving the EVEBRA treatment. All patients will receive the same qualitative AFT reconstruction surgery by trained plastic surgeons.

Possible consequences:
- This technique is still a rising one, results can be difficult to to predict
- The injected volume can decrease in a way that the reconstructed breast will stay smaller than the healthy breast
- During this study, patients will undergo 3 operations during this reconstruction period. De reconstruction period is therefore prolongued (estimated * - 1 year), because of the need for repeated surgeries. We expect that repeated surgeries won't be necessary in the future, because of the use of autologous tissue.
- If randomized to EVEBRA intervention group: wearing of EVE device can be experienced as a burden. EVEBRA will be used for a total of 4 weeks (2 weeks before- and 2 weeks after each surgery)
- If randomized to the control group: not wearing of the EVE device does not lead to any medical risks. It is possible that an extra surgery is necessary, this will be discussed with your plastic surgeon.
- Extra measurements, for the evaluation of the breast reconstruction. No medical risk related.
- Hospitalization

Burden:
- 2x extra controls, time 20 min.
- 3x questionnaires, time 10 min.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Female gender - Age of 18 years and older - History or in candidate for a mastectomy procedure in the near future - Patients undergoing preventive mastectomy - Patients* choice to undergo a breast reconstruction - Wanting to participate in this study - Patient is able to wear the external expansion device

Exclusion criteria

• untreated breast cancer
• history of radiation therapy on the involved breast, even if it was part of a previous breast conservation procedure
• completed chemotherapy course less than 2 months prior
• except for the biopsy leading to the diagnosis of cancer, had surgery to breast prior to the mastectomy
• had mastectomy wound healing complications
• mastectomy defect/scar has significant skin excess and deep folds adherent to the chest wall
• has a pacemaker or aneurysm clips

• pregnancy or breastfeeding
• had a cardiac stent placed within the last 2 months
• claustrophobic
• known current substance abuse
• history of silicone allergy
• history of Gadolinium allergy
• history of lidocaine allergy
• bleeding diathesis, whether primary or iatrogenic
• cigarette smoker and/or Smokeless cigarette smokers
• medical conditions that preclude breast reconstruction including uncontrolled hypertension or diabetes, renal failure, steroid dependent asthma, and on immuno- suppressant medications, as reported by patient

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-07-2021
Enrollment:	90
Type:	Actual

Medical products/devices used

Generic name:	External Vacuum Expansion Device
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	23-03-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-04-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	06-12-2022
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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05003635
CCMO	NL72809.068.20