Autologous fat transfer: introduction of a full breast reconstructive method

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This study 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...

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

Summary

ID

NL-OMON55230

Source
ToetsingOnline

Brief title
BREAST-II

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: Zorginstituut Nederland & ZonMw,Zorgonderzoek Nederland (ZON)

Intervention

Keyword: Autologous fat transfer, Breast cancer, Breast reconstruction, Lipofilling

Outcome measures

Primary outcome

The patients* quality of life will be the main outcome measure of this study, using the BREAST-Q questionnaire.

Secondary outcome

The quality of the breast reconstruction will be measured by the volume and shape over time (3D photography or MRI), patient satisfaction (questionnaire) and aesthetic judgement (panel rating pre- and post operative photos). Complications during treatment and follow-up will be registered and compared. Oncological follow-up will be studied, with patients undergoing imaging over a period of 5 years. At last, a cost-effectiveness analysis will be performed to research the economic characteristics of this new technique.

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.

Study objective

This study 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

A multicentre cohortstudy will determine the efficacy and safety of the AFT technique. AFT covers the actual surgical technique to transfer fat cells to the breast.

Intervention

See study design

Study burden and risks

As this technique is not applied in everyday practice in the Netherlands, we expect that the benefits for the patients is the opportunity to have her breast reconstructed with this autologous fat transfer (AFT) technique. Current literature suggests less complications using AFT compared to using implants in breast reconstruction.

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

- Active smoker or a history of smoking 4 weeks prior to surgery
- Current substance abuse
- History of lidocaine allergy
- History of silicone allergy
- 4 weeks or less after chemotherapy
- History of radiation therapy in the breast region
- Oncological treatment includes radiotherapy after mastectomy
- Kidney disease
- Steroid dependent asthma (daily or weekly) or other diseases
- Immune-suppressed or compromised disease
- Uncontrolled diabetes
- BMI>30
- Large breast size (i.e. larger than cup C), unless the patient prefers reduction of the contralateral side towards Cup C
- Extra-capsular silicone leaking from the encapsulated implant from a previous breast reconstruction
- The treating plastic surgeon has strong doubts on the patient*s treatment compliance

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-12-2020
Enrollment:	350
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	25-09-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-12-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-12-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-05-2024

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	NCT04261829
CCMO	NL72808.068.20