Deep inferior epigastric perforator flap breast reconstruction with or without inguinal lymph node transplant for treatment of breast cancer related arm lymphedema:
A multicenter randomized controlled trial

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23459

Source
NTR

Brief title
DIEPLY

Health condition

lymphedema

Sponsors and support

Primary sponsor: n.a.
Source(s) of monetary or material Support: n.a.

Intervention

Outcome measures

Primary outcome

Degree of lymphedema at affected arm measured by Inverse water volumetry and difference in mobility and ROMrange of motion .:

Secondary outcome

Patient reported satisfaction and Quality of Life as measured by multiple questionnaires:
- Range of motion of the shoulder joint in the following directions: abduction, ante flexion, retro flexion, medial and lateral rotation
- Lymph-ICF questionnaire
- The Breast-Q reconstruction Module

Study description

Background summary

Although the prevalence of breast cancer related lymphedema (BCRL) has decreased over the years, BCRL remains a very debilitating, devastating complication which is hard to treat. At this moment, most patients with lymphedema are treated conservatively. Surgical interventions for lymphedema are divided in reductive and reconstructive treatment. For reconstructive treatment as lympho-venous anastomosis and or free lymph node transplantations are performed. In this study we want willto evaluate if combining a standard DIEP-flap breast reconstruction (BR) combined with an inguinal lymph node transplant will lead to an improvement of the BCRL

The aim of this study is to evaluate investigate whether BCRL will improve in patients with BCRL undergoing DIEP-flap BR combined with an inguinal lymph node transplant have statistically significant improvement of their BCRL (primary objective), and Quality of life (secondary objective) compared to the patients group receiving a solemnly DIEP-flap BR without an inguinal lymph node transplant. Furthermore, this study will investigate the Quality of life (secondary objective) in these two patient groups.

Study objective

combining a standard DIEP-flap breast reconstruction (BR) with an inguinal lymph node transplant will lead to an improvement of the BCR

Study design

pre- surgery,

2 weeks post surgery,
6 weeks post surgery
6 months post surgery,
12 months post surgery

Intervention

an inguinal lymph node transplant during the standard DIEP- flap breast reconstruction

Contacts

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Eligibility criteria

Inclusion criteria

• All patients with complaints of lymphedema with an indication for secondary BR
• Persistent volume excess of more than 5-10% of the affected arm (arm at side of mastectomy) in comparison to the contralateral arm measured by inverse water volumetry with pitting oedema
• Persistent volume excess of the affected arm, patients are in maintenance phase of treatment for BCRL
• Good patient coherence and willingness to wear therapeutic garments
• Operability

Exclusion criteria

• Recurrent malignancy
• Lipoedema of the upper extremetiesextremities
• Lymphedema of the lower extremetieextremity(s)

• Patients with untreated lymphedema
• Patients with bilateral upper arm lymphedema

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-11-2020
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	12-10-2020
Application type:	First submission

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
NTR-new	NL8965
Other	METC UMCG : METc 2020/427

Study results