

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

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23459

Bron

NTR

Verkorte titel

DIEPLY

Aandoening

lymphedema

Ondersteuning

Primaire sponsor: n.a.

Overige ondersteuning: n.a.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 to 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 solely 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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Recurrent malignancy
- Lipoedema of the upper extremities
- Lymphedema of the lower extremity(ies)
- Patients with untreated lymphedema

- Patients with bilateral upper arm lymphedema

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-11-2020
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies	
Datum:	12-10-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register

NTR-new

Ander register

ID

NL8965

METC UMCG : METc 2020/427

Resultaten