Has Manual Lymphatic Drainage (MLD), immediately applied after the axillary dissection during 5 months, a preventive effect on the development of arm lymphedema

Gepubliceerd: 13-09-2007 Laatst bijgewerkt: 13-12-2022

1. Patients, receiving MLD and exercises after breast cancer surgery with axillary dissection are less at risk to develop an arm lymphedema, compared with patients receiving only exercises; 2. Patients, receiving MLD and exercises after breast...

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

Samenvatting

ID

NL-OMON22079

Bron
NTR

Verkorte titel
Study Prevention Armoedema

Aandoening

Breast cancer, lymphedema, prevention, manual lymphatic drainage
Borstkanker, lymfoedeem, preventie, manuele lymfedrainage

Ondersteuning

Primaire sponsor: Katholieke Universiteit Leuven
Faculteit Bewegings- en Revalidatiewetenschappen
Overige ondersteuning: Institute for the Promotion of Innovation by Science and Technology in Flanders (IWT) - Toegepast Biomedisch onderzoek met een primaire Maatschappelijke finaliteit (TBM)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Incidence of arm lymphedema: defined by > 200 ml increase of the arm volume compared with the preoperative value.
All patients from the control group and from the experimental group are measured first preoperatively and then 1 month, 3 months, 6 months, 1 year and 2 years after the breast surgery.

Toelichting onderzoek

Achtergrond van het onderzoek

Aim: To examine if MLD, applied postoperatively on breast cancer patients, has an influence on the development of lymphedema.
Patients: All patients with an invasive breast cancer are measured preoperatively. The patients with a unilateral axillary dissection are asked to participate in the study. Power analyse has showed that at least 146 patients have to participate.
Method: The patients are randomly allocated to the experimental group, receiving MLD and exercises, or the control group, receiving only exercises. Both groups are treated during 5 months either in our hospital or by a physiotherapist in the periphery. They undergo preoperatively and 1, 3, 6 and 12 months after the breast surgery the following measurements: arm volume and shoulder mobility. The patients fill in the 'LYMF-SBP' questionnaire, to score the functioning problems of the patient. Forty patient volunteers, equally divided between both groups, undergo also a lymphoscintigraphy before the start of the therapy, immediatly after and 6 months after the therapy.

Doel van het onderzoek

1. Patients, receiving MLD and exercises after breast cancer surgery with axillary dissection are less at risk to develop an arm lymphedema, compared with patients receiving only exercises;

2. Patients, receiving MLD and exercises after breast cancer surgery with axillary dissection have less functioning problems, compared with patients receiving only exercises;

3. Patients, receiving MLD and exercises after breast cancer surgery with axillary dissection have more visible axilloaxillary anastomoses after 5 months of therapy and have more visble rerouting of lymphatics from the arm to the trunk, compared with patients receiving only exercises;

4. Patients, receiving standardised MLD performed by a specialist in lymphedema therapy (in our hospital), develop less frequently arm lymphedema, compared with patients receiving MLD performed by a physiotherapist in the periphery.

Onderzoeksproduct en/of interventie

1. In the periphery: not standardised;

2. In our hospital: standardised;

Control group: Exercises.

Experimental group: Exercises + MLD.

Exercises: The patient performs an exercise schema independently at home. The physiotherapist performs mobilisations of the shoulder and verifies of the patient does her exercises well and follows the exercise schema. Duration of 1 session is 30 min, frequency is 1 / week, total amount of sessions is 20.

MLD: MLD method Leduc and method Vodder is applied in a standardised matter. Duration of 1 session is 30 min, frequency is variable between 1 / week and 3 / week, total amount of sessions is 40.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients who had primary breast surgery with axillary dissection in the University Hospital Leuven (UZ Leuven).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients who had breast surgery with sentinel procedure;

2. Patients with bilateral axillary dissection;

3. Patients not measured preoperatively;

4. Patients who refuse to participate in the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2007
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-09-2007
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	ID
NTR-new	NL1023
NTR-old	NTR1055
Ander register	: IWT 060519
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
No