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

No registrations found.

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

Summary

ID

NL-OMON22079

Source
NTR

Brief title
Study Prevention Armoedema

Health condition

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

Sponsors and support

Primary sponsor: Katholieke Universiteit Leuven
Faculteit Bewegings- en Revalidatiewetenschappen
Source(s) of monetary or material Support: Institute for the Promotion of Innovation by Science and Technology in Flanders (IWT) - Toegepast Biomedisch onderzoek met een primaire Maatschappelijke finaliteit (TBM)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Functioning problems of the patients.
At each measurement session the patient fills in the 'LYMF-SBP questionnaire'. This is a reliable and valid questionnaire that scores the consequences of an arm lymphedema in terms of 'International Classification of Functioning Disability and Health'.

Shoulder mobility: anteflexion, abduction, functional exo- and endorotation (also each measurement session).

Visible axillo-axillary anastomoses and visible rerouting of lymphatics from the arm to the trunk.
Patients are asked to undergo a lymphoscintigraphic examination at the following points in time: before the start of the therapy, after 5 months of therapy and 6 months later. We want to include 20 patients in the experimental group and 20 patients in the control group.

Study description

Background summary

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.

Study objective

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.

Intervention

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.

Contacts

Public
UZ Leuven
Dienst Fysische Geneeskunde en Revalidatie

Herestraat 49
Nele Devoogdt
Leuven 3000
Belgium
0032 (0) 16 348550
Scientific
UZ Leuven
Dienst Fysische Geneeskunde en Revalidatie
Herestraat 49
Nele Devoogdt
Leuven 3000
Belgium
0032 (0) 16 348550

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2007
Enrollment:	160
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-09-2007
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	NL1023
NTR-old	NTR1055
Other	: IWT 060519
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
No