Prevalence, severity and origin of lymphedema among women five years after treatment for breast cancer.

Gepubliceerd: 06-05-2008 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON23930

Bron
NTR

Verkorte titel
PAL-study

Aandoening

Prevalentie
Lymfoedeem
Borstkanker
Chronisch

Prevalence
Lymphedema
Breast cancer
Chronic

Ondersteuning

Primaire sponsor: afdeling Heelkunde, Academisch ziekenhuis Maastricht
Overige ondersteuning: Geen fondsen, geen financien

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary end goal is to determine the presence of lymphedema among female patients five years after the treatment for breast cancer. The water replacement technique is used to measure the arm volume. When the difference between the two arms is bigger than 150ml or 200ml, lymphedema is diagnosed.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

This scientific research is important, because the survival rate of patients with breast cancer has increased, thanks to very early diagnostics and new treatment possibilities. Due to the higher survival rate, patients have more problems with the postoperative complications of the treatment for breast cancer. One of the most common complications is lymphedema. This has a strong negative effect on the quality of life. Therefore it is important that the cause, risk factors, the severity of lymphedema, disabilities and the effect of the treatment for lymphedema are investigated. Goal of this investigation is preventing lymphedema and making therapy possible in an early stage. In this way complications can be reduced to a minimum or even prevented

Objective of the study:

The primary goal is investigating the number of women that have lymphedema five years after the treatment for breast cancer.

In the describing part of this study, the focus will be on the correlation between lymphedema and 1) surgical treatment, 2) additional therapies, 3) risk factors for lymphedema. Besides these first four goals attention will be paid to 4) the degree and the severity of edema, 5) the functional consequences and 6) earlier treatment and its result on the consequences of the treatment for breast cancer.

Study design:

The study design is a retro- and prospective cohort study. The prevalence, severity and nature of lymphedema will be determined among women five years after treatment for breast cancer.

Study population:

266 women are selected to participate in this research. They visited the “mammapoli” for the first time in the period from January 2001 till December 2002 and were diagnosed with breast cancer. If the breast cancer reoccurs, the patient will be excluded from further research.

Intervention (if applicable):

Primary study parameters/outcome of the study:

The primary end goal is to determine the presence of lymphedema among female patients five years after the treatment for breast cancer. The water replacement technique is used to measure the arm volume. When the difference between the two arms is bigger than 150ml or 200ml, lymphedema is diagnosed.

Secundary study parameters/outcome of the study (if applicable):

Status research
Outcome parameters are: absence or presence of lumpectomy, ablation, microdochectomy, sentinel node procedure, axillary lymph node dissection, radiotherapy (chest, armpit), chemotherapy, hormonal therapy and TNM classification.

Questionnaires and conversation

The scores of the EORTC QLQ-BR23 en EORTC QLQ-C30 questionnaires will be noted as an outcome. (For questionnaires see appendix 1 and 2)

Outcome parameters are: absence or presence of risk factors and of therapy for lymph edema and this result will be used as an outcome. (For questionnaires see appendix 3 and 4)

Physical examination

As an outcome the absence or presence of overweight, sensibility, mobility and strength will be noted.

The stage of the lymphedema will be determined as defined by the Society For Lymphology. Results will be processed in a database.

When there is lymphedema present, the preference location will be determined by measuring the circumference. The outcome is presence of lymphedema on a specific part of the arm.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):
The participating patients are in no extra risk of complications caused by the study. The patients will come once for one hour to the AZM for a conversation, to fill out questionnaires and a physical examination. No invasive examination will take place. During the physical check up the arms are inspected and palpated and the range of motion, arm volume, sense of touch, strength are measured. Questionnaire subjects are: quality of life after (breast) cancer, risk factors for lymphedema and therapy for complications after the treatment for breast cancer. The participants will receive the result of the test. When there are complications, an advice for therapy will be given. Because of the low risk that patients have by participating in this study, a dispensation of insurance has been asked for.

Onderzoeksopzet

The patient must come once to the Academisch Ziekenhuis in Maastricht

Onderzoeksproduct en/of interventie

Status research

Absence or presence of lumpectomy, ablation, microdochectomy, sentinel node procedure, axillary lymph node dissection, radiotherapy (chest, armpit), chemotherapy, hormonal therapy and TNM classification.

Questionnaires and conversation
EORTC QLQ-BR23 and EORTC QLQ-C30 questionnaires will be scored.

Absence or presence of risk factors and of therapy for lymph edema and this result will be scored in a questionaire.

Physical examination:

BMI and sensibility, mobility and strength of the shoulder, elbow and hand will be tested.

The stage of the lymphedema will be determined as defined by the Society For Lymphology, by inspection of the arm.
When there is lymphedema present measuring the circumference will be done.
The water replacement technique is used to measure the arm volume. When the difference between the two arms is bigger than 150ml or 200ml, lymphedema is diagnosed.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Wemon who visited the “mammapoli” for the first time in the period from January 2001 till December 2002 and were diagnosed with breast cancer.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

If the breast cancer reoccurs, the patient will be excluded from further research. If the patient is death, she will be exluded.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2008
Aantal proefpersonen:	266
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-05-2008
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	NL1262
NTR-old	NTR1308
Ander register	Heelkunde, AZM : 21458
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A