

The efficacy of physiotherapy upon shoulder function following axillary dissection in breast cancer: a pilot study

Submission date 26/02/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 26/02/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 05/09/2007	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Study information

Scientific Title

Study objectives

Physiotherapy is effective in patients with mastectomy and Axillary Lymph Node Dissection (ALND), for shoulder/arm mobility and pain primarily and quality of life secondarily.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added as of 05/09/2007: The regional medical ethics board approved the study.

Primary study design

Interventional

Study design

Randomised, active controlled, parallel group, single blinded multicentre trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Breast cancer

Interventions

Patients assigned to the treatment group started physiotherapy two weeks following surgery in a private practice of their own choice. The research assistant contacted the physiotherapist who had to comply with the treatment regime and supplied him or her with information regarding the project and treatment guidelines. This information consisted of:

1. A guideline containing advice and exercises for arm/shoulder, posture correction, coordination exercises, exercises for muscular strength and improvement of the general physical condition
2. Exercises to prevent lymph oedema
3. Instruction for scar massage if necessary
4. A registration form to report the content of the treatment sessions and a three-point scale to indicate whether the amount of treatment sessions was sufficient

The total number of treatments was nine (nine being usually covered by the healthcare insurance), once or twice weekly for the first three weeks, thereafter once a fortnight or less. Patients were asked to perform home exercises on a daily basis for approximately ten minutes a day.

Patients assigned to the control group received a leaflet flyer with advice and exercises for the arm/shoulder for the first weeks following surgery and had no further personal contact with a physiotherapist.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Shoulder mobility (flexion [0 - 180°], abduction [0 - 180°]), measured by use of a digital inclinometer under standardised conditions
2. Pain in the shoulder/arm, measured using the VAS score (zero to ten, zero = no pain, ten = unbearable pain)

Key secondary outcome(s)

1. Disabilities in daily life, measured by the DASH (Disabilities of the Arm, Shoulder and Hand) questionnaire (zero to 100, zero = no functional problems, 100 = maximal problems)
2. Oedema (ml), measured in both arms by means of water displacement, grip strength (Kg) of both hands, measured using the hand-held dynamometer and quality of life, as measured by the SIP (Sickness Impact Profile-short version) questionnaire (zero to 68, zero = good health status, 68 = sever physically disabled)

Completion date

04/11/2004

Eligibility

Key inclusion criteria

1. 18 years of age and older
2. Breast cancer with an ALND
3. A Visual Analogue Scale (VAS)-pain score (zero to ten) of one minimally
4. Moderate shoulder disabilities in daily life (minimal three points on a five points disability score list)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Key exclusion criteria

1. Patients with a previous contra-lateral mastectomy
2. Patients with insufficient knowledge of the Dutch language to fill in the questionnaires

Date of first enrolment

11/08/2003

Date of final enrolment

04/11/2004

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Centre Nijmegen (UMCN)

Nijmegen

Netherlands

6500 HB

Sponsor information

Organisation

University Medical Centre Nijmegen (UMCN) (The Netherlands)

ROR

<https://ror.org/05wg1m734>

Funder(s)

Funder type

Other

Funder Name

Not provided at time of registration

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	30/08/2007		Yes	No