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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/02/2007	**Overall study status** Completed	
Last Edited 05/09/2007	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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.

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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 measure
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)

Secondary outcome measures
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)

Overall study start date
11/08/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
30

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)

Sponsor details
Department of Physiotherapy
Nijmegen
Netherlands
6500 HB

Sponsor type
Hospital/treatment centre

ROR

https://ror.org/05wg1m734

Funder(s)

Funder type
Other

Funder Name
Not provided at time of registration

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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