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Lymphoedema prevention in breast cancer

Submission date 24/09/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/10/2008	**Overall study status** Completed	
Last Edited 15/09/2015	**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

Protocol serial number
ID1124

Study information

Scientific Title
Lymphoedema prevention in breast cancer: a simple blind, randomised, prospective clinical trial of the efficacy of early physical therapy

Study objectives

Physical therapy could be an effective measure to prevent lymphoedema in patients undergoing breast cancer surgery including axillary lymph-node dissection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Principe de Asturias Hospital's Human Research Ethics Committee approved the study in February 2005

Study design
Prospective randomised single-centre controlled single-blinded trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breast cancer

Interventions
Intervention group:
Physical including a manual lymph-drainage technique, progressive massage of the scar, and progressive active and action-assisted shoulder exercises started in conjunction with functional activities and proprioceptive neuromuscular facilitation without resistance and educational strategy including instruction with printed materials about the lymphatic system, concepts of normal load versus overload, lymphoedema source, the identification of possible precipitating factors, etc.

Control group:
Educational strategy including instruction with printed materials about the lymphatic system, concepts of normal load versus overload, lymphoedema source, the identification of possible precipitating factors, etc.

In order to use the same ES in both groups, a consensus was achieved before starting the study. In both groups patients were taken immediately after hospital discharge to either the EPT or to the CG programs. Both programs consisted of a three-week period with three visits per week. Each participant was assessed pre-operatively prior to randomisation and then post-operatively on hospital discharge (between day 3 and day 5), 4 weeks, and 3, 6 and 12 months after surgery.

This intervention study was conducted as a single-blinded randomised-controlled trial, as the physical therapist performing follow-up assessments remained blinded to the group allocation of the subjects.

Intervention Type
Other

Phase

Not Specified

Primary outcome(s)
Circumference measurements of the upper limbs using a standard 1 cm wide, at 5 cm intervals from the elbow fold pre-operatively prior to randomisation and then post-operatively on hospital discharge (between day 3 and day 5), 4 weeks, and 3, 6, 12 and 24 months after surgery.

Key secondary outcome(s))
1. Pain, measured using the Visual Analogue Scale (VAS) score (0 = no pain, 10 = unbearable pain) pre-operatively prior to randomisation and then post-operatively on hospital discharge (between day 3 and day 5), 4 weeks, and 3, 6, 12 and 24 months after surgery
2. Range of shoulder abduction using a digital goniometer pre-operatively prior to randomisation and then post-operatively on hospital discharge (between day 3 and day 5), 4 weeks, and 3, 6, 12 and 24 months after surgery

Completion date
15/05/2009

Eligibility

Key inclusion criteria
1. Consecutive women diagnosed with breast cancer and undergoing unilateral surgery with axillary lymph-node dissection at the Principe de Asturias Hospital in Alcala de Henares, Madrid (Spain)
2. Aged 18 to 70 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Without axillary lymph-node dissection or with bilateral breast cancer (BC)
2. Systemic disease
3. Locoregional recurrence
4. Any contraindication to physical therapy

Date of first enrolment
15/05/2005

Date of final enrolment
15/05/2009

Locations

Countries of recruitment
Spain

Study participating centre
Universidad de Alcala
Alcala de Henares, Madrid
Spain
28871

Sponsor information

Organisation
The Carlos III Health Institute (Instituto de Salud Carlos III) (Spain)

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Government

Funder Name
The Carlos III Health Institute (Instituto de Salud Carlos III) (Spain) (ref: PI071124)

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	12/01/2010		Yes	No
Results article	results	01/02/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes