

Lymphoedema prevention in breast cancer

Submission date 24/09/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/10/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/09/2015	Condition category Cancer	<input type="checkbox"/> 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

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?
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Results article	results	12/01/2010	Yes	No
Results article	results	01/02/2015	Yes	No