

An investigation into the relationship between postoperative arm and shoulder mobilisation exercises and the incidence of lymphoedema

Submission date 02/07/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 02/07/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/05/2012	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jacquelyne Todd

Contact details
Lymphoedema Department
Wharfedale Hospital
Newall Carr Road
Otley
Leeds
United Kingdom
LS21 2LY
+44 (0)113 3921807
Jacquelyne.Todd@leedsth.nhs.uk

Additional identifiers

Protocol serial number
PRF/02/1

Study information

Scientific Title

A randomised comparative trial of two programmes of shoulder exercise following axillary node dissection for invasive breast cancer

Acronym

LASER (Leeds Axillary Surgery Exercise Research)

Study objectives

Please note that, as of 19/06/2008, this trial record was extensively amended. Most of the changes can be found in the relevant field. The following changes have also been made:

1. Scientific trial title was added
2. Study hypothesis was added
3. Anticipated end date has been updated from 31/12/2003 to 31/12/2007

Study hypothesis:

There is a reduced incidence of lymphoedema after post-operative exercise that delays full shoulder mobilisation for one week.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added as of 19/06/2008: This study was approved by the West Leeds Research Ethics Committee.

Primary study design

Interventional

Study design

Randomised comparative trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Breast cancer related lymphoedema

Interventions

Interventions amended as of 19/06/2008:

Intervention group will receive a shoulder mobilisation programme that is characterised by a delayed commencement of full range gleno-humeral exercises following the removal of the axillary drain.

Control group will receive the current standard exercise regimen which commences full range gleno-humeral exercises from the first post-operative day.

Measurements for both groups are pre-operatively and at one year, with structured telephone questionnaires at one week, one month and six months.

Previous interventions:

Intervention group will receive a shoulder mobilisation programme that is characterised by a delayed commencement of full range gleno-humeral exercises following the removal of the axillary drain.

Control group will receive the current standard exercise regimen which commences full range gleno-humeral exercises from the first post-operative day.

Measurements for both groups are pre-operatively, one month, six months and one year.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Added as of 19/06/2008:

1. Limb volume using water displacement method

Key secondary outcome(s)

Added as of 19/06/2008:

1. Range of movement using goniometer
2. Hand grip strength using dynamometer
3. Health related quality of life using FACTB+4, Shoulder Disability Questionnaire

Completion date

31/12/2007

Eligibility

Key inclusion criteria

Patients who are undergoing axillary surgery followed by radiotherapy for unilateral primary breast cancer with axillary node involvement.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Added as of 26/06/2008:

1. Women under eighteen years

2. Existing history of breast cancer
3. Prior axillary surgery or irradiation
4. Pre-existing lymphoedema as measured by a difference in 200 mls between the two arms when measured pre-operatively using the volume displacement method
5. Women requiring full time cognitive or physical care

Date of first enrolment

01/01/2003

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Lymphoedema Department

Leeds

United Kingdom

LS21 2LY

Sponsor information

Organisation

Physiotherapy Research Foundation (UK)

ROR

<https://ror.org/04sn78z72>

Funder(s)

Funder type

Charity

Funder Name

Physiotherapy Research Foundation (Ref: PRF/02/1)

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	01/12/2008		Yes	No