ISRCTN38946256 https://doi.org/10.1186/ISRCTN38946256

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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/07/2003	**Overall study status** Completed	
Last Edited 29/05/2012	**Condition category** Cancer	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

Study design
Randomised comparative trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Added as of 19/06/2008:
1. Limb volume using water displacement method

Secondary outcome measures
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

Overall study start date
01/01/2003

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

Age group
Adult

Sex
Female

Target number of participants
Added as of 19/06/2008: 104 participants (52 per group)

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
England

United Kingdom

Study participating centre
Lymphoedema Department
Leeds
United Kingdom
LS21 2LY

Sponsor information

Organisation
Physiotherapy Research Foundation (UK)

Sponsor details
The Chartered Society of Physiotherapy
14 Bedford Row
London
United Kingdom
WC1R 4ED
+44 (0)20 7306 6601
attewm@csp.org.uk

Sponsor type
Charity

Website
http://www.csp.org.uk

ROR
https://ror.org/04sn78z72

Funder(s)

Funder type
Charity

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

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	01/12/2008		Yes	No