

An investigation into the relationship between full range arm and shoulder mobilisation and the incidence of lymphoedema.

Submission date 30/09/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/09/2012	Condition category Circulatory System	☐ 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
N0436130486

Study information

Scientific Title

Study objectives

To compare the incidence of lymphoedema development in breast cancer patients undertaking graded postoperative arm exercise compared to standard early full range shoulder exercise.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Lymphoedema postmasectomy

Interventions

Randomised controlled trial

Random allocation to:

1. Graded post-operative arm exercise
2. Standard early full range shoulder exercise

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Height
2. Weight
3. Limb volume
4. Truncal oedema
5. Range of movement at the gleno-humeral joint
6. Arm swelling
7. Truncal swelling
8. Measurement of shoulder mobility

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/06/2005

Eligibility

Key inclusion criteria

Patients admitted for unilateral mastectomy and axillary node clearance who have been treated by the Breast Surgeons at Leeds General Infirmary (LGI).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/04/2003

Date of final enrolment

30/06/2005

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Macmillan Lymphodema Specialist Office

Leeds

United Kingdom

LS16 6QB

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Leeds Teaching Hospitals NHS Trust (UK)

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