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

Recruitment status No longer recruiting	Prospectively registered		
	☐ Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category	[] Individual participant data		
	No longer recruiting Overall study status Completed		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

 ${\bf Clinical Trials. gov\ number}$

Secondary identifying numbers

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

- 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

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2003

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

Age group

Adult

Sex

Female

Target number of participants

Not provided at time of registration

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

England

United Kingdom

Study participating centre
Macmillan Lymphodema Specialist Office
Leeds
United Kingdom
LS16 6QB

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Leeds Teaching Hospitals NHS Trust (UK)

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