

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

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/09/2012	<b>Condition category</b> Circulatory System	<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**  
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

### **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?
<a href="#">Results article</a>	results	01/12/2008		Yes	No