ISRCTN61345521 https://doi.org/10.1186/ISRCTN61345521

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

Submission date	Recruitment status	[_] Prospectively registered
30/09/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/09/2012	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.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