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Prevention of lymphoedema after clearance by external compression

Submission date	Recruitment status	[ ] Prospectively registered
28/10/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/10/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/07/2020	Cancer	[ ] Record updated in last year

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-preventing-lymphoedema-after-surgery-to-remove-lymph-nodes-under-arm-place

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
9074

Study information

Scientific Title

Prevention of lymphoedema after axillary clearance by early external compression: a multicentre randomised interventional treatment trial

Acronym
PLACE

Study objectives
The purpose of this multi-centre trial is to test the efficacy of external graduated compression garments in preventing the onset of lymphoedema 18 months after axillary node clearance for node positive breast cancer in women who develop an arm volume increase of 4-8.9% within the first six months post surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NW 8 Research Ethics Committee - Greater Manchester South on 21/05/2010, ref: 10/H1003/35

Primary study design
Interventional

Study design
Multicentre randomised interventional treatment trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Breast Cancer; Disease: Breast

Interventions
Intervention:
Application of a graduated compression garment to the affected arm together with standard management for 12 months.

Control:
Standard management for arm swelling (written advice, arm elevation, and massage).

Total duration of trial: 12 months
Follow up length: 12 months
Study Entry: single randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

Incidence of lymphoedema (greater than 10% arm volume increase compared to contralateral arm) at 2 and 5 years after axillary node clearance (assessed by perometer scanning).

Key secondary outcome(s)
1. Quality of life (TOI and FACT B+4)
2. Costs of individual strategies (EQ5D utility measures)
3. Incidence of infection/lymphangitis at 2 years after surgery
4. Arm movement

Completion date
01/04/2015

Eligibility

Key inclusion criteria
1. Women aged 18 - 90 years
2. Early breast cancer (no evidence of metastatic disease by local screening procedures), scheduled to undergo axillary node clearance
3. Consented to pre-surgical arm measurements by perometer and develop arm volume increases of 4 - 8.9% within 6 months after surgery
4. Willing to attend for follow-up visits per the trial schedule
5. Written informed consent to enter the PLACE trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Any patients with no pre-surgical baseline measurements
2. Known distant metastasis
3. Inoperable breast cancer (T4 category or distant metastasis)
4. Node negative not undergoing axillary clearance
5. Previous axillary radiotherapy
6. Past history of breast/chest wall radiotherapy
7. Previous axillary clearance, either unilateral or bilateral
8. Participation in another clinical trial of local therapy that may affect the results obtained in this study
9. Pregnancy

Date of first enrolment
01/10/2010

Date of final enrolment
01/04/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospital of South Manchester
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
University Hospital of South Manchester (UK)

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration