

Prevention of lymphoedema after clearance by external compression

Submission date 28/10/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/07/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

Mrs Charlotte Stockton

Contact details

University Hospital of South Manchester
Nightingale Centre and Genesis Prevention Centre
Southmoor Road
Manchester
United Kingdom
M23 9LT
+44 (0)161 291 4040
charlotte.stockton@uhsm.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Multicentre randomised interventional treatment trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

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).

Secondary outcome measures

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

Overall study start date

01/10/2010

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

Planned sample size: 270

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

England

United Kingdom

Study participating centre

University Hospital of South Manchester

Manchester

United Kingdom

M23 9LT

Sponsor information

Organisation

University Hospital of South Manchester (UK)

Sponsor details

Nightingale Centre and Genesis Prevention Centre

Southmoor Road

Manchester

England

United Kingdom

M23 9LT

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Andrew.maines@manchester.ac.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.uhsm.nhs.uk/Pages/default.aspx>

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

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