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Prospective Randomised, Crossover Evaluation of the Flexitouch™ in comparison with standard treatment for Secondary Arm Lymphoedema

Submission date
11/05/2005

Recruitment status
No longer recruiting

Registration date
11/05/2005

Overall study status
Completed

Last Edited
04/10/2017

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
79787

Study information

Scientific Title
Prospective Randomised, Crossover Evaluation of the Flexitouch™ in comparison with standard treatment for Secondary Arm Lymphoedema

Study objectives
Not provided at time of registration

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)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Breast cancer associated lymphoedema

Interventions
The active treatment phases were comprised of maintenance therapy with the Flexitouch™ alone or with MLD alone, respectively, as an adjunct to the daily use of the compression garment. Each treatment modality was utilised for one hour daily during 14 consecutive days of treatment. Each phase of active treatment was preceded by a 1 week treatment washout, with use of the garment alone (no MLD). The sequence of treatment was randomly assigned; the initial modality of therapy was followed, after the washout phase, by crossover to the alternate treatment modality.

Intervention Type
Device

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2003

Completion date
30/09/2004

Eligibility

Key inclusion criteria
Patients with lymphoedema of the upper extremity after surgical and/or radiotherapeutic interventions for breast carcinoma were eligible for enrollment. Recruitment was undertaken from the population of patients who presented to the Stanford Center for Lymphatic and Venous Disorders.

Inclusion criteria:
To be eligible for enrollment, a subject was required to have evidence of unilateral, breast cancer-associated lymphoedema, with an increase of at least 10% in the measured volume of the affected arm when compared with the contralateral, normal limb. All subjects were required to have completed an initial treatment phase of limb volume reduction through intensive decongestive physiotherapy administered by a trained physiotherapist. A minimum of 30 days must have elapsed following the completion of initial treatment, which was required to include instruction in self-administered, maintenance manual
lymphatic drainage (MLD) and the subsequent use of a properly fitted compression garment.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
Exclusion criteria included the presence of any of the following: bilateral lymphoedema of the upper extremity; active cancer; active infection; clinical evidence of venous obstruction or active thrombophlebitis; pulmonary oedema; congestive heart failure; a history of pulmonary embolism; or the presence of any other relative contraindication to
the use of the lymphedema treatment modalities employed in this investigation.

Date of first enrolment
01/12/2003

Date of final enrolment

30/09/2004

Locations

Countries of recruitment
United States of America

Study participating centre
Stanford University
Stanford, CA
United States of America
94305

Sponsor information

Organisation
Stanford University Institutional Review Board (USA)

Sponsor details
Stanford University
Research Compliance Office
1215 Welch Road, Modular A
Stanford, CA
United States of America
94305

Sponsor type
University/education

ROR
https://ror.org/00f54p054

Funder(s)

Funder type
University/education

Funder Name
Stanford University (USA)

Alternative Name(s)
Stanford, Leland Stanford Junior University, SU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

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	29/03/2006		Yes	No