ISRCTN26438275 https://doi.org/10.1186/ISRCTN26438275

Effectiveness of acupuncture, special dressings and simple, low-adherence dressings for healing venous leg ulcers in primary healthcare: Study protocol for a cluster-randomised controlled clinical trial

Submission date 16/05/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 30/05/2008	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 30/12/2020	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

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
EC0790215 / 0052/2007

Study information

Scientific Title
Effectiveness of acupuncture, special dressings and simple, low-adherence dressings for healing venous leg ulcers in primary healthcare: Study protocol for a cluster-randomised controlled clinical trial

Study objectives
The combination of compression bandaging with simple, low-adherence dressings and acupuncture is more effective than when the same bandaging is employed in combination with special dressings or with simple, low-adherence dressings, but no sensory stimulation (acupuncture), with respect to the complete healing of venous leg ulcers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Andalusian Government Committee for Clinical Trials, Spain. Date of approval: 08/05/2007 (ref: acta 03/07)

Study design
Prospective, open, multicentre, cluster randomised trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Venous leg ulcer

Interventions
The participating primary healthcare centres will be randomly allocated to the following three groups:

Group A: Compression therapy + low-adherence, simple dressings + acupuncture
Group B: Compression therapy + special dressings
Group C: Compression therapy + low-adherence, simple dressings

Compression therapy (Groups A, B and C):
Compression therapy will be given to all the participants in the study. Once the patient has been examined and the ankle/arm index calculated by means of a Doppler scan, an evaluation will be made of the state of the skin and of the shape of the leg, after confirming the absence of neuropathology, arterial pathology and cardiac insufficiency. The bandaging will be of a class 3, high-compression multilayer type, following cleansing and application of the dressing, as follows:
1. With a 50% overlap, apply a cotton bandage in a spiral pattern from the base of the toes to just below the knee, without imposing any tension
2. Apply an elastic bandage in a spiral pattern, with 50% overlap and stretched to 50% of its extension, from the base of the toes to just below the knee
3. Apply a cohesive elastic bandage, with 50% overlap and stretched to 50% of its extension, from the base of the toes to just below the knee, and apply light pressure to ensure the adherence of the bandage. The oedema of the leg should be reduced by raising the limb for 15 minutes before applying compression.

Cleansing of the ulcer for the patients given low-adherence, simple dressings (Groups A and C):
1. Cleaning: with running water and mild soap, followed by careful drying
2. Debridement: if necrotic tissue or sloughing are observed, perform enzymatic debridement, which may be combined with excision debridement, if necessary
3. Managing infection: if infection is suspected, take a sample and begin treatment with Silvederma® for a maximum of 2 weeks. If a culture study confirms the infection, treat using oral antibiotics
4. Dressings: simple, low-adherence type (paraffin-impregnated tulle gras)

Topical treatment of the ulcer for the patients given special dressings (Group B):
1. Cleaning: with running water and mild soap, followed by careful drying
2. Debridement: if necrotic tissue or sloughing are observed, perform enzymatic debridement, which may be combined with hydrogel to favour autolysis. If necessary, excision debridement should be applied.
3. Managing infection: if infection is suspected, take a sample and begin treatment with silver dressings (hydrofibre or hydropolymer) for a maximum of 2 weeks. If a culture study confirms the infection, treat using oral antibiotics.
4. Dressings: Cover with hydropolymers. Use alginate or hydrofibre dressings if exudate must be controlled.

Sensory stimulation by acupuncture (Group A):
The nursing staff will be trained in the specific techniques of localisation, puncture and manipulation in order to apply acupuncture at the perilesional zone of the ulcer(s), in healthy skin, using 4-8 needles, and at 2 points located on either side of the tibial crest of the affected limb (Yinlingquan SP9 and Zusanli ST36). The sensorial stimulation sessions will be applied for the first 3 months of this treatment programme or until the ulcer has completely healed. If complete healing is not achieved in this period, the sessions may be prolonged for another 3 months, after which the sensorial stimulation treatment will be discontinued. For each session, the number of needles used and the exact location of their application will be recorded. A priori, the ulcer should be cleansed once weekly, the same frequency as the sensorial stimulation. Nevertheless, this may be increased or decreased, at the discretion of the nursing staff.

Duration of interventions: Interventions will continue until the ulcer is completely cured, except acupuncture which may be prolonged up to 6 months (maximum).
Total duration of follow-up: 12 months

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Time to complete healing.

Secondary outcome measures
1. Complete healing at 3 months after beginning treatment
2. Changes in the size of the surface area of the ulcer, assessed at 3, 6 and 12 months
3. Pain intensity measured on a visual analogue scale, assessed at 3, 6 and 12 months
4. Health-related quality of life, assessed using the 12-item Short Form health survey (version 2) at 3, 6 and 12 months

Overall study start date
01/04/2008

Completion date
01/12/2010

Eligibility

Key inclusion criteria
1. Both males and females, no age limit
2. Patients with venous leg ulcers who request treatment by a medical professional (doctor or nurse) at one of the Primary Healthcare Clinics in the Sevilla-Sur Health District taking part in the study, with at least one active venous leg ulcer (open, clinical, etiological, anatomical, pathological classification [CEAP] C6) with a diameter exceeding 1 cm

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
375

Key exclusion criteria

1. Arterial pathology (systolic pressure in the ankle of less than 80 mmHg or ankle/arm systolic index less than 0.8)
2. Diabetic ulcer of the foot, rheumatoid arthritis or systemic vasculitis
3. Use of anticoagulants
4. Pregnancy

Date of first enrolment
01/04/2008

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
Spain

Study participating centre
Pain Treatment Unit
Dos Hermanas
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Sponsor information

Organisation
Carlos III Health Institute (Spain)

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Sponsor type
Research organisation

Website
http://www.isciii.es/htdocs/en

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Research organisation

Funder Name
Carlos III Health Institute, Healthcare Research Fund (Project No. EC0790215) (Spain)

Funder Name
Andalusian Regional Ministry of Health (Project No. 0052/2007) (Spain)

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?
Protocol article	protocol	11/06/2008	30/12/2020	Yes	No