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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

Registration date
30/05/2008

Overall study status
Completed

Last Edited
30/12/2020

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jorge Vas

Contact details
Pain Treatment Unit
Primary Healthcare Centre
Segovia s/n
Dos Hermanas
Spain
41700
-
jorgef.vas.sspa@juntadeandalucia.es

Additional identifiers

Protocol serial number
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)

Primary study design
Interventional

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

Study type(s)
Treatment

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(s)
Time to complete healing.

Key secondary outcome(s)

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

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

Healthy volunteers allowed
No

Age group
Other

Sex
All

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
Spain
41700

Sponsor information

Organisation
Carlos III Health Institute (Spain)

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

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