

A randomised controlled trial of two bandages for treating venous leg ulcers

Submission date 25/04/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 25/04/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 24/08/2009	Condition category Circulatory System	☐ 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

Protocol serial number
HTA 96/12/26

Study information

Scientific Title

Study objectives

Compression bandaging is the mainstay of venous leg ulcer treatment, however the optimal bandage regimen is unclear and there are large variations in practice. The 4 layer bandage (4LB) is used widely in the UK but is discarded after a single use and is relatively expensive. The short-stretch bandage (SSB) is the standard bandage in Europe, and is reusable. A recent systematic review demonstrated the paucity of RCTs in this area, and those that exist are of poor quality. The review also showed that multilayer bandaging is more effective than single layer; high compression systems such as the 4LB and SSB are more effective than low compression systems; however the two trials that have compared SSB and 4LB were vastly underpowered and did not incorporate an economic analysis. This study proposes to compare the 4LB and SSB systems in a two-arm pragmatic RCT involving 400 patients with venous ulcers. Patients will be followed up until healing or for a maximum period of 30 months.

Substantial benefits to the NHS and patients will occur if the trial demonstrated one of the bandages is superior to the other; substantial resource savings would occur in bandage expenditure if it were shown that the SSB was of at least equivalent effectiveness to the 4LB.

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

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Varicose veins/ulcers

Interventions

1. 4 layer bandage
2. Short stretch bandage

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Proportion of ulcers completely healed; healing rates; costs; quality of life; recurrence rates at 12 months.

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/01/2002

Eligibility

Key inclusion criteria

Patients with leg ulcers

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/10/1998

Date of final enrolment

31/01/2002

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department of Health Sciences

York

United Kingdom

YO10 5DD

Sponsor information

Organisation

Department of Health (UK)

ROR

<https://ror.org/03sbpja79>

Funder(s)**Funder type**

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

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?
Results article	results	01/10/2004		Yes	No