

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

<b>Submission date</b> 25/04/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/04/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/08/2009	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Nicky Cullum

**Contact details**  
Department of Health Sciences  
University of York  
Alcuin College  
Area 2  
Seebohm Rowntree Building  
Heslington  
York  
United Kingdom  
YO10 5DD  
+44 (0)1904 321343  
nac2@york.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

### Participant information sheet

### 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 measure**

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

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/10/1998

**Completion date**

31/01/2002

**Eligibility****Key inclusion criteria**

Patients with leg ulcers

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

400

**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

England

United Kingdom

## Study participating centre

Department of Health Sciences

York

United Kingdom

YO10 5DD

# Sponsor information

## Organisation

Department of Health (UK)

## Sponsor details

Quarry House

Quarry Hill

Leeds

United Kingdom

LS2 7UE

+44 (0)1132 545 843

Sheila.Greener@doh.gsi.gov.uk

## Sponsor type

Government

## Website

<http://www.dh.gov.uk/en/index.htm>

## ROR

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

# Funder(s)

## Funder type

Government

## Funder Name

## 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?
<a href="#">Results article</a>	results	01/10/2004		Yes	No