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

Submission date
25/04/2003

Recruitment status
No longer recruiting

Registration date
25/04/2003

Overall study status
Completed

Last Edited
24/08/2009

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

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

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) id 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

Primary study design
Interventional

Study design
Randomised controlled trial

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