

Is the Short-stretch bandage or the 4-layer bandage more effective in treating leg ulcers?

Submission date 01/03/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 01/03/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 22/05/2013	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

ClinicalTrials.gov (NCT)
NCT00202267

Protocol serial number
MCT-63175

Study information

Scientific Title

Community randomised controlled trial on the effectiveness of two compression bandaging technologies

Acronym

CBT (Canadian Bandaging Trial)

Study objectives

To determine whether there is a 4 weeks or greater improvement in time-to-healing with short-stretch bandages compared to the four-layer bandaging system; the time to complete healing of the reference ulcer (one year randomisation, follow-up to 30 months).

As of 08/05/2009 this record was updated to include changes to the protocol. All changes can be found under the relevant field. At this time the anticipated end date of this trial was also updated; the initial end date at the time of registration was 30/09/2007.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics Board of Queen's University Health Sciences and Affiliated Teaching Hospitals, Kingston, Ontario (Canada) approved on the 8th July 2003. Renewed annually.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Venous ulcer (leg)

Interventions

Four-layer bandage versus short-stretch bandage for four weeks with a follow-up until 12 months after healing in some cases until a maximum of 30 months

Trial details received: 12 Sept 2005.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Time-to-healing of the reference ulcer (comparison of four-layer and short-stretch over 4 week period)

Key secondary outcome(s)

Current information as of 08/05/2009:

Over a one-year follow-up:

1. Rate of reduction in ulcer area for a maximum of 30 months
2. Proportion of ulcers healed at 12 and 24 weeks in each arm
2. Durability of Healing: Recurrence rates during 12 months after healing
3. Quality of life (McGill Short Form Pain Questionnaire; SF-12; EuroQol on five dimensions- Mobility, self care, usual activities, pain/discomfort and anxiety depression) at 12 months after healing
4. Expenditures for treatment

Initial information at time of registration

Over a one-year follow-up:

1. Rate of reduction in ulcer area for a maximum of 30 months
2. Recurrence rates during 12 months after healing
3. Quality of life (McGill Short Form Pain Questionnaire; SF-12; self-administered survey) at 12 months after healing
4. Expenditures for treatment

Completion date

31/12/2009

Eligibility

Key inclusion criteria

Current information as of 08/05/2009:

1. 18 years or older, either sex, ability to communicate in English
2. Could provide written informed consent
3. Had an ulcer of a minimum duration of 1 week
4. Had a clinical presentation of venous insufficiency
5. Had a leg ulcer that measured 0.7 cm in any one dimension
6. Ankle brachial pressure index greater than or equal to 0.8

Initial information at time of registration

1. 18 years or older, either sex, ability to communicate in English
2. Leg ulcer greater than 1 cm in any one dimension, minimum duration of 1 week, Ankle Brachial Pressure Index (ABPI) greater than 0.7

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Current information as of 08/05/2009:

1. Had diabetes (taking insulin or an oral hypoglycaemic)
2. Had failed to improve over a 3-month period after being treated with either bandaging systems prior to the trial
3. Had been a previous study patient
4. Were cognitively impaired

Initial information at time of registration

1. Diagnosis of diabetes mellitus
2. Participants who failed to improve over a 3-month period after being treated previously with either of the trial treatments
3. Previous trial patients
4. Cognitive impairment

Date of first enrolment

11/01/2003

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

Canada

Study participating centre

Professor, School of Nursing

Kingston

Canada

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Sponsor information

Organisation

Queen's University (Canada)

ROR

<https://ror.org/02y72wh86>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-63175)

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	02/10/2012		Yes	No