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

Submission date	Recruitment status	[_] Prospectively registered
01/03/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/03/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/05/2013	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00202267

Secondary identifying numbers
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.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
11/01/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Added as of 08/05/2009: 424 (previously 414)

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
K7L 3N6

Sponsor information

Organisation
Queen's University (Canada)

Sponsor details
207 Stuart St
Kingston
Canada
K7L 3N6

Sponsor type
University/education

Website
http://www.queensu.ca/

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

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?
Results article	results	02/10/2012		Yes	No