Randomized controlled clinical study to assess the clinical efficacy of the 3M* Coban* 2 Layer Compression System compared to a short-stretch compression bandage in the treatment fo venous leg ulcers

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The objective of the study is to evaluate the clinical efficacy of 3M* Coban* 2 Layer Compression System in the treatment of venous leg ulcers compared to Rosidal® K shortstretch compression bandage (Lohmann & Rauscher, Rengsdorf, Germany).

Ethical review	Approved WMO
Status	Completed
Health condition type	Skin vascular abnormalities
Study type	Interventional

Summary

ID

NL-OMON31099

Source
ToetsingOnline

Brief title
Compression therapy of venous leg ulcer

Condition

- Skin vascular abnormalities
- Venous varices

Synonym
treatment of venous leg ulcer

Research involving
Human

Sponsors and support

Primary sponsor: 3M Deutschland GmbH, Medical Markets Laboratory
Source(s) of monetary or material Support: 3M

Intervention

Keyword: clinical efficacy, compression therapy, venous leg ulcer

Outcome measures

Primary outcome

Primary endpoint is the complete study ulcer-healing rate (defined as number complete study ulcer healed divided by the total number of subjects) the treatment period of up to 12 weeks. The wound healing status will be assessed clinically and documented during every visit for bandage change. Wound status and ulcer size will be recorded and photo documented. Final assessment of ulcer healing will be blinded. Complete ulcer healing is defined as complete re-epithelialization of the study ulcer.

Secondary outcome

Secondary endpoints are the health related quality of life, as assessed using the Cardiff Wound Impact Schedule (CWIS) at enrollment and end of treatment, and a treatment cost calculation, based on material costs and cost for nursing and doctor visits. Additional endpoints are time to complete ulcer closure, bandage wear time, reduction in ulcer size and safety (adverse event documentation).

Study description

Background summary

Venous leg ulcers are a common clinical problem that increases in prevalence as thepopulation ages. They are typically a recurring condition and compression therapy is considered the most effective treatment for such ulcers; in addition, it is generally believed that compression is also beneficial to reduce the recurrence of this condition. The cost of chronic venous leg ulcers is high because of the ongoing care that they require, and the quality of life of the subjects is jeopardized by this condition. Adequate treatment is effective at improving the quality of life in these subjects. A new quality of life tool (the Cardiff Wound Impact Schedule) has been developed specifically for leg ulcers and diabetic foot ulcers.

The efficacy of a compression bandage is related to how well it holds in place to provide continued adequate compression and to subject acceptance. The more comfortable the bandage is, the more likely the subjects are to wear it as prescribed and to obtain the expected benefit in terms of wound healing. This protocol compares a new compression bandage with an established short-stretch compression bandage to evaluate the efficacy with respect to healing rate (primary endpoint) during a 12-week treatment period.

Study objective

The objective of the study is to evaluate the clinical efficacy of 3M* Coban* 2 Layer Compression System in the treatment of venous leg ulcers compared to Rosidal® K shortstretch compression bandage (Lohmann & Rauscher, Rengsdorf, Germany).

Study design

This study will be a prospective, randomized controlled study with blinded assessment of the primary endpoint. Suitable patients will be randomly allocated to one compression therapy system based on the size of the ulcer: 3M* Coban* 2 Layer Compression System or Rosidal® K short-stretch compression bandage. Subjects will be given a randomization number which serves as a unique identifier of the subject. When both legs require compression therapy, both legs receive the same compression therapy. An indendent reviewer, who is blinded to the subjects treatment, will reassess the healing endpoint.

Study duration:
Each subject will be followed for a treatment period of up to 12 weeks including a minimum of 13 visits required if treated is performed for a period of 12 weeks. Due to early healing of the study ulcer the participation of a

subject could be shorter.

Intervention

Not applicable

Study burden and risks

The patient needs to attend to study site every 7 days to get the bandages changed. If necessary the bandages can be changed more often. The patient will then have to fill in a memory card in order to keep track of the intermittend bandage changes. He will have to fill in a Quality of life qestionnaire at the beginning and at the end of the study.

The risks include the possibility of experiencing following side effects: pain, inflammation, irritation, skin damage, allergic reactions. Moreover the wound condition may not heal while taking part in the study.

The potential benefit is that the product may prove to be more effective than the other products. The bandage may require changing less often, which mean less discomfort for the patient and less disruption to the natural healing process. The treatment costs can be optimized.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Subjects having a venous leg ulcer (stage C6 according CEAP classification, venous pathology proved by the presence of reflux (Pr)), which is at least 1 cm in any dimension but not larger than 10 cm in any dimension and has at least 5 cm distance to additional ulcers.

Exclusion criteria

Subjects with an ABPI < 0.8 as measured within four weeks prior enrollment

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	06-02-2008
Enrollment:	60

Type:	Actual

Medical products/devices used

Generic name:	3M Coban 2 Layer Compression System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-10-2007
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL18918.096.07