

Efficacy and safety of K-Two® versus Actico® compression system in the management of venous leg ulcers: a pilot study

Submission date 20/04/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/06/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 26/07/2016	Condition category Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
UK-08-10-3102343

Study information

Scientific Title
Evaluation of the efficacy and the safety of the K-Two® versus Actico® compression systems in the management of venous leg ulcers: a randomised parallel group open label pilot study

Study objectives

To compare the therapeutic efficacy and the safety of two multilayer compression systems, K-Two® versus Actico®, in the treatment of venous leg ulcers through a randomised controlled clinical trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised parallel-group open-label pilot trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Venous leg ulceration

Interventions

Patients will be randomised to either an Actico® bandage or K-Two® bandage system. Follow up will be to a maximum of 12 weeks, or until the trial ulcer heals.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Complete ulcer closure (100% re-epithelialisation) at 12 weeks at the latest.

Key secondary outcome(s)

1. The time to reach complete ulcer closure
2. The percentage of patients with a reduction of 40% of the leg ulcer area at the last available evaluation compared to baseline
3. The time required to reach this percentage reduction of 40%
4. The absolute leg ulcer surface area reduction (area t0 - area tlast) after the 12 weeks of treatment by the studied compression systems
5. The complete ulcer closure of the studied ulcerated limb
6. The complete ulcer closure of all ulcers located both in studied and controlateral limbs, if existing
7. The local safety of the studied compression systems (emergent local adverse events [LAE])
8. The acceptability of the studied compression systems, by the investigator (characteristics of care dispensed) and by the patient (assessment of pain during dressing changes and between dressing changes)
9. The change frequency of the studied compression systems during the study

10. The slippage of the compression systems at each bandage change
11. The ankle circumference measurements at the following visits: D0, W1, W4 and W12 or at the trial withdrawal in order to follow the evolution of an oedema of the lower limb, if existing
12. The patient's quality of life at baseline and at the end of the treatment period (week 12 or at the end of the treatment whatever reason), using a generic toll, the Venous Leg Ulcer Quality of Life Questionnaire (VLU QoL) in accordance with a standard protocol

Completion date

18/11/2010

Eligibility

Key inclusion criteria

1. Patients over 18 years old, either sex, who have provided his written informed consent
2. Patient who can be followed by the same investigating team for the 12 weeks treatment period
3. Patient who agrees to concord to the study/wear this type of multilayer compression system for at most one week
4. Patient presenting an ankle circumference included between 18 to 32 cm
5. Ulcer between 2 and 50 cm² in surface
6. Ulcer duration between 1 and 24 months, for a new leg ulcer (not recurrent)
7. Ulcer duration under 24 months, for a recurrent leg ulcer
8. Venous or mixed leg ulcer (Ankle Brachial Pressure Index greater than 0.8 and less than 1.3 in both legs at inclusion)
9. Ulcer at least 3 cm, from any other wound located on the same limb
10. Leg ulcer treated by a contact layer as a primary dressing (Urgotul®)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Patient participating in another clinical trial
2. Female patient of childbearing age who does not have any mode of contraception and is able to become pregnant during the study period
3. Patient with known hypersensitivity to one of the components of the tested compression systems
4. Patient with known hypersensitivity to the interface primary dressing (Urgotul®)
5. Patient presenting a neoplastic lesion treated by radiotherapy or chemotherapy or patients

treated with immunosuppressive drugs or high-dose corticosteroids

6. Patient who has undergone surgery directly related to his/her venous insufficiency in the 2 months prior to inclusion
7. Patient with a history of deep or superficial vein thrombosis in the 3 months prior to inclusion
8. Patient confined to bed
9. Ulcer for which surgery is scheduled in the 12 weeks after inclusion
10. Ulcer which is clinically infected
11. Ulcer surface area totally (100% of surface) covered with dry fibrinous tissue (sloughy tissue) at inclusion or black necrotic plaque covering more than 10% of ulcer area
12. Cancerous ulcer

Date of first enrolment

18/05/2009

Date of final enrolment

18/11/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

CRICP

London

United Kingdom

SW15 5ES

Sponsor information

Organisation

Laboratoires Urgo (France)

ROR

<https://ror.org/04z0bfr53>

Funder(s)

Funder type

Industry

Funder Name

Laboratoires Uργο (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration