ISRCTN47210331 https://doi.org/10.1186/ISRCTN47210331

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 26/06/2009	**Overall study status** Completed	
Last Edited 26/07/2016	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Christine Moffatt

Contact details
CRICP
174 Huntingfiled Road
London
United Kingdom
SW15 5ES

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

Study design
Randomised parallel-group open-label pilot trial

Primary study design
Interventional

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 cm^2 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 neoplasic 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 Urgo (France)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes