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

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| **Submission date**<br>20/04/2009 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>26/06/2009 | **Overall study status**<br>Completed | |
| **Last Edited**<br>26/07/2016 | **Condition category**<br>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**

**Secondary identifying numbers**
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

### Secondary study design
Randomised parallel trial

### Study setting(s)
Other

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### 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 measure

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

### Secondary outcome measures
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

### Overall study start date
18/05/2009

### 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

### Age group

Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
232 (116 in each arm)

### 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
England

United Kingdom

### Study participating centre
**CRICP**
London
United Kingdom
SW15 5ES

# Sponsor information

**Organisation**
Laboratoires Urgo (France)

**Sponsor details**
42, Rue de Longvic
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F-21300

**Sponsor type**
Industry

**Website**
http://www.urgo.com/

**ROR**
https://ror.org/04z0bfr53

# Funder(s)

**Funder type**
Industry

**Funder Name**
Laboratoires Urgo (France)

# 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