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Octenidine gel plus a hydrogel dressing compared with a silver alginate dressing for venous leg ulcers: a randomized clinical trial

Submission date
26/12/2025

Recruitment status
No longer recruiting

Registration date
30/12/2025

Overall study status
Completed

Last Edited
29/12/2025

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Venous leg ulcers are chronic wounds caused by problems with blood flow in the leg veins. They can be slow to heal and often recur. Many different dressings are used in practice, so it is important to know which approaches lead to better healing. This study aims to compare, over 4 weeks, two dressing regimens for venous leg ulcers: (1) octenidine gel plus a hydrogel dressing versus, and (2) a silver-containing calcium alginate dressing.

Who can participate?
Patients aged 18–80 years with a venous leg ulcer that has not healed for more than 3 months and has an area of 20–60 cm²

What does the study involve?
At the start (baseline) and again after 4 weeks, each participant's ulcer is assessed using the RESVECH 2.0 scale. RESVECH 2.0 is a standardised wound assessment that scores: wound dimensions (as categories within the scale), depth/affected tissues, wound edges, tissue type in the wound bed, exudate, and signs of infection/inflammation (including features consistent with biofilm). The total score is the sum of these elements; a lower score indicates a better/healed wound.
At dressing changes in both groups, the wound is cleansed using an antiseptic solution containing 0.1% polyhexanide and poloxamer 188, followed by mechanical debridement if needed (e.g., using a sterile Volkmann spoon). Participants then receive either:
1. Experimental group: octenidine gel applied to the ulcer bed and covered with a hydrogel dressing, or
2. Control group: a silver-containing calcium alginate dressing.
Dressings are replaced every 3 days for 4 weeks.

What are the possible benefits and risks of participating?
Possible benefits include regular wound assessment and treatment that may improve wound healing. Possible risks include local skin irritation, discomfort during dressing changes or debridement, allergic reactions to dressing components (octenidine or silver), and general risks

associated with chronic wounds (e.g., infection or delayed healing). Participants are monitored and appropriate medical care is provided if needed.

Where is the study run from?
The study is run from Jan Długosz University in Częstochowa (Poland), with participant treatment/data collection carried out at:
1. The Surgical Outpatient Clinic of the Healthcare Centre of Jan Paweł II District Hospital in Włoszczowa
2. The Wound Treatment Clinic of the Specialist Hospital of Priest B. Markiewicz, Subcarpathian Oncology Centre in Brzozów.

When is the study starting and how long is it expected to run for?
June 2024 to June 2025

Who is funding the study?
Jan Długosz University in Częstochowa (Poland)

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
Clinical effectiveness of octenidine gel with hydrogel dressing compared with silver-containing calcium alginate dressing in venous leg ulcers: randomized trial

Acronym
OCTAS-VLU

Study objectives
To compare the clinical effectiveness of two dressing regimens for venous leg ulcers (VLUs) — octenidine-based gel plus a hydrogel dressing versus a silver-containing calcium alginate dressing — over a 4-week treatment period, using the RESVECH 2.0 scale (total score).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/09/2015, Ethics Committee of the Medical University of Silesia in Katowice (Poniatowskiego 15, Katowice, 40-055, Poland; +48 (0)32 208 35 46; kombioet@sum.edu.pl), ref: KNW/0022/KB1/100/I/15

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Chronic venous leg ulcers (VLUs)

Interventions
Randomisation was implemented using sequentially numbered, sealed opaque envelopes containing the group allocation. Envelopes were opened only after a participant had been enrolled/consented.

Experimental intervention (Arm A): Octenidine gel + hydrogel dressing
At each dressing change, the wound was cleansed with an antiseptic solution containing 0.1% polyhexanide and poloxamer 188, followed by mechanical debridement with a sterile Volkmann spoon as required. Octenidine gel was then applied to the ulcer bed and covered with a hydrogel dressing. Dressings were replaced every 3 days for 4 weeks.

Control intervention (Arm B): Silver-containing calcium alginate dressing
The same wound cleansing and debridement procedure was used (0.1% polyhexanide + poloxamer 188; Volkmann spoon debridement as required). A silver-containing calcium alginate dressing was applied. Dressings were replaced every 3 days for 4 weeks.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Octenidine gel (octenidine dihydrochloride) + hydrogel dressing , silver-containing calcium alginate dressing

Primary outcome(s)
1. Wound healing status/wound severity (overall wound condition) measured using RESVECH 2.0 scale (total score) at baseline and 4 weeks

Key secondary outcome(s))

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. Diagnosis of venous leg ulcer (VLU); non-venous origin excluded by Doppler ultrasonography
2. Chronic wound treated unsuccessfully for >3 months
3. Wound area 20–60 cm²
4. Written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Allergy to octenidine or silver
2. No written informed consent

Date of first enrolment
01/06/2024

Date of final enrolment
01/06/2025

Locations

Countries of recruitment
Poland

Sponsor information

Organisation
Jan Długosz University

ROR
https://ror.org/0566yhn94

Funder(s)

Funder type

Funder Name
Jan Długosz University

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available