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Cellulose membrane dressing for hard-to-heal venous leg ulcers

Submission date	Recruitment status	[_] Prospectively registered
19/12/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/12/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
29/12/2025	Skin and Connective Tissue Diseases	[X] Record updated in last year

Plain English summary of protocol

background and study aims

Venous leg ulcers are long-lasting wounds that happen when blood doesn't flow properly through the veins in the legs. They can be painful and slow to heal. This study is looking at whether a new type of dressing made from bacterial cellulose (called Bioprocess®) works as well or better than a commonly used silver-based dressing (Suprasorb A + Ag). Both dressings are designed to protect the wound and help it heal.

Who can participate?

Adults who have a venous leg ulcer confirmed by a Doppler ultrasound scan. Participants must be suitable for outpatient care and compression therapy.

What does the study involve?

People who join the study will be randomly placed into one of two groups. One group will have their ulcer treated with the bacterial cellulose dressing, and the other group will have the silver-based dressing. In both groups, the wound will be cleaned with saline, covered with gauze, and treated with compression bandages. Participants will visit the clinic once a week until their ulcer heals. The size of the ulcer will be measured every week.

What are the possible benefits and risks of participating?

Taking part may help your ulcer heal and give you access to regular care. However, there is no guarantee that your ulcer will heal faster. Both dressings are commonly used and considered safe, but as with any treatment, there is a small risk of irritation or allergic reaction.

Where is the study run from?

The study is being carried out in two outpatient surgical centres in Poland.

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

The study started in February 2022 and is expected to finish in September 2024.

Who is funding the study?

Investigator initiated and funded

Who is the main contact?
ikingaxd@gmail.com
e.rojczyk@ujd.edu.pl

Contact information

Type(s)
Public, Scientific

Contact name
Miss Kinga Spyrka

ORCID ID
https://orcid.org/0000-0003-4897-8000

Contact details
Jan Dlugosz University in Czestochowa
Czestochowa
Poland
42-200
+48 501193857
ikingaxd@gmail.com

Type(s)
Public, Scientific, Principal investigator

Contact name
Miss Ewa Rojczyk

ORCID ID
https://orcid.org/0000-0002-2977-5542

Contact details
Jan Dlugosz University in Czestochowa
Czestochowa
Poland
42-200
+48 605466076
e.rojczyk@ujd.edu.pl

Additional identifiers

Study information

Scientific Title
Topical application of a bacterial cellulose membrane (Bioprocess®) versus a silver-containing calcium alginate dressing (Suprasorb A + Ag) for chronic venous leg ulcers: a randomised controlled study

Acronym
BC-VLU

Study objectives
Primary objective: To compare the effectiveness of a bacterial cellulose membrane dressing (Bioprocess®) versus a silver-containing calcium alginate dressing (Suprasorb A + Ag), both used with standard compression therapy, in adults with chronic venous leg ulcers.
Secondary objectives: To compare the rate of ulcer area reduction over time and the proportion of ulcers completely healed during follow-up.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/10/2013, Regional Scientific Research Commission in Katowice, SUM, KB124/2013 (Regional Scientific Research Commission in Katowice (SUM), Katowice, 40-055, Poland; +48 32 208 3600; nauka@sum.edu.pl), ref: KB124/2013

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 (VLU)

Interventions
Arm 1 (Intervention): Bacterial cellulose membrane dressing (Bioprocess®; Biofil, Curitiba, Brazil) applied to the ulcer after saline irrigation, extending ~1 cm beyond wound margins, covered with sterile gauze; compression bandaging applied (target pressure 25–35 mmHg). Weekly physician review; ulcer area measured every 7 days by planimetry.
Arm 2 (Control): Silver-containing calcium alginate dressing (Suprasorb A + Ag; Lohmann & Rauscher) applied after saline irrigation, covered with sterile gauze; compression bandaging as above (25–35 mmHg). Dressing replaced daily until healing; weekly physician review; ulcer area measured every 7 days by planimetry.
Co-interventions (both arms): Standard wound cleansing (saline), debridement as clinically

indicated, and standard pharmacotherapy for chronic venous disease (micronized flavonoid fraction: diosmin 450 mg + hesperidin 50 mg daily).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Bioprocess® (bacterial cellulose membrane dressing) vs Suprasorb® A + Ag (silver-containing calcium alginate dressing).

Primary outcome(s)
1. Time to complete ulcer healing measured using Ulcer area (cm^2) measured by planimetry (wound tracing using a digitiser) at baseline and every 7 days; change over time calculated from serial measurements at Baseline and every 7 days (weekly) until complete healing (up to 16 weeks).

Key secondary outcome(s))

Completion date
01/09/2024

Eligibility

Key inclusion criteria
1. Adults (≥18 years)
2. Presence of a chronic venous leg ulcer (VLU) on the lower limb, confirmed by Doppler ultrasonography
3. Ankle–brachial index (ABI) within the acceptable/normal range
4. Eligible for standard compression therapy and outpatient follow-up
5. Prior standard care (e.g., compression and conventional dressings) without complete healing before enrolment
6. 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
100

Key exclusion criteria
1. Non-venous ulcers (e.g., arterial, diabetic foot, vasculitic, malignant ulcers)
2. Clinically significant arterial disease / ABI < 0.7 or > 1.3
3. Active severe wound infection requiring systemic antibiotics at baseline
4. Known allergy to dressing components (bacterial cellulose, alginate, silver)
5. Pregnancy or breastfeeding
6. Inability to provide informed consent or comply with compression therapy/follow-up

Date of first enrolment
01/02/2022

Date of final enrolment
01/09/2024

Locations

Countries of recruitment
Poland

Sponsor information

Organisation
Jan Długosz University in Czestochowa

Organisation
Specialist Hospital No. 2 in Bytom

Organisation
John Paul II District Hospital in Włoszczowa

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available