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Comparative study in adults with pressure ulcer stage I

Submission date	Recruitment status	[_] Prospectively registered
20/08/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/09/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/09/2025	Skin and Connective Tissue Diseases	[X] Record updated in last year

Plain English summary of protocol
Background and study aims
A pressure ulcer is a localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear and/or friction. These wounds occur frequently among individuals who have difficulty moving, or cannot reposition themselves, such as the frail elderly, individuals undergoing surgery, or individuals with spinal cord injury. However, anyone of any age could develop a pressure ulcer if they are exposed to prolonged, unrelieved pressure and shear forces. Comprehensive assessment of the individual and his or her pressure ulcer informs the development of the most appropriate management plan and ongoing monitoring of wound healing. Currently in clinical practice pressure ulcers are monitored using the clinical judgment of a health professional supported by pressure ulcer assessment tools. A pressure ulcer classification system is used to aid in the description of the extent of skin and tissue damage presenting as a pressure ulcer. Treatment for pressure ulcers varies depending on the grade of the ulcer. The aim of this study is to evaluate the safety and effectiveness of EHO-85 (SKINDOX®) vs hyperoxygenated fatty acid in patients with stage I pressure ulcers.

Who can participate?
Patients aged over 18 years with stage I pressure ulcers

What does the study involve?
Participants will be randomly allocated to treatment with SKINDOX® (EHO-85) or hyperoxygenated fatty acids. The aim is to evaluate the safety and effectiveness of the two treatments. Participants will receive the assigned treatment according to standard care practices. The study includes three visits for a duration of 45 days to assess the condition of the skin, discomfort level, quality of life and any adverse events.

What are the possible benefits and risks of participating?
This product may be beneficial for the regeneration of tissues and the improvement of metabolic processes. The participants did not receive any specific and/or direct benefits from participating in this study. There are no known risks in using this product. However, it is recommended not to use the product in the case of individual hypersensitivity or allergy to one or more components.

Where is the study run from?
Noventure S.L. (Spain)

When is the study starting and how long is it expected to run for?
January 2024 to October 2024

Who is funding the study?
Noventure S.L. (Spain)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Protocol Number: CBSNOV03052023

Study information

Scientific Title
Open-label, multicenter clinical study to evaluate the safety and efficacy of EHO-85 (SKINDOX®) vs hyper-oxygenated fatty acid in adult patients diagnosed with pressure ulcer stage I

Study objectives
Primary objectives:
To assess the efficacy of EHO 85 (SKINDOX®) versus hyperoxygenated fatty acid in reducing the clinical symptomatology associated with pressure ulcer stage 1.

Secondary objectives:
To assess the safety and effectiveness of EHO 85 (SKINDOX®) versus hyperoxygenated fatty acid by collecting the safety events that occur during product administration until study closure.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 15/01/2024, Local Ethics Committee for Clinical Trials of S.C. Syncro Clinical Research S.R.L. (Str. Stadionului no. 16, Brașov, 500064, Romania; +40 (0)368 006 915; contact@syncromedic.ro), ref: 77/15.01.2024

2. approved 19/04/2024, Local Ethics Committee for Clinical Trials at Medical Centre Prolet LTD (25 Olimpi Panov Str., Rousse, 7000, Bulgaria; +359 (0)887 842 514; med.center.prolet@gmail.com), ref: 000000026/19.04.2024

Study design
Open-label multicenter comparative clinical study

Primary study design
Observational

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Pressure ulcer stage I

Interventions
Each patient signed the informed consent form for participating in the study. After the consent signature, the data collection started. The doctors collected prospective data related to the clinical efficacy and safety. The following assessment tools were used during the study:
1. VAS QoL (0-100 mm Visual Analogue Scale score)
2. Discomfort evaluation
3. Transparent Disc Technik assessment
4. Braden Scale score
5. Satisfaction in using the product

Patients who are eligible for the study treatment will receive EHO 85 (SKINDOX®) or hyperoxygenated fatty acid. The products will be allocated 1:1. Each product will be administered for a period of 2 weeks.

EHO-85 (SKINDOX®):
The product was applied two to three times daily on risk or susceptible areas, spreading it gently with the fingertips and massaging to facilitate absorption. Hands were washed after each application. The product was administered for a period of 2 weeks. In case Braden scale was present equal or higher risk in developing pressure ulcers, than it was decided to continue on product administration for 1 month.

Hyperoxygenated fatty acid (Corpitol Emulsion):
The necessary amount of Corpitol Emulsion was applied on the red, dry area at risk of ulceration. This was repeated two to three times a day. The product was gently spread and massaged to help the penetration of the Corpitolinol 60 microparticles. The product was administered for a period of 2 weeks. In case Braden scale was present equal or higher risk in developing pressure ulcers, then it was decided to continue on product administration for 1 month.

Visit 2 (Day 14) took place after 2 weeks of product administration. During this visit (V2), the investigator evaluated the risk of developing PU using the Braden Scale. In case any risk was determined, the investigator has the possibility to advise product administration for an additional month. Additionally, at Visit 3 (Day 45), the investigator evaluated the satisfaction in product utility through a 5-point Likert scale: 1- Very Unsatisfied; 2- Unsatisfied; 3- Neutral; 4- Satisfied; 5- Very Satisfied.

Intervention Type
Other

Primary outcome(s)
1. Transparent Disc Technik (TDT) measured at Visit 1 (Day 0), Visit 2 (Day 14) and Visit 3 (Day 45)
2. Quality of life measured using a Visual Analogue Scale (from 0 mm - very low to 100 mm - very high) at Visit 1 (Day 0), Visit 2 (Day 14) and Visit 3 (Day 45)

Key secondary outcome(s))
1. Time to quality of life improvement measured using the VAS QoL (from 0 mm - very low to 100 mm - very high), recorded at each visit (Visit 1 [Day 0], Visit 2 [Day 14] and Visit 3 [Day 45]), and calculated as the time from baseline (Visit 1 [Day 0]) to the first observed improvement
2. Time to discomfort level reduction measured using a 7-point Likert scale (1 = Totally unacceptable to 7 = Perfectly acceptable), assessed at Visit 1 (Day 0), Visit 2 (Day 14) and Visit 3 (Day 45). Time to reduction is calculated as the interval from baseline to the first recorded improvement in score
3. Proportion of patients experiencing adverse events (AEs) recorded throughout the entire study period (Visit 1 to Visit 3) using AE forms

Completion date
07/10/2024

Eligibility

Key inclusion criteria
Adult patients (>18 years) with pressure ulcer stage 1 (non-blanching erythema [category I PU])

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
50

Key exclusion criteria
1. Hypersensitivity or individual allergy to one or more components of the product
2. Known drug and/or alcohol abuse
3. Known medical history of peripheral artery disease
4. Other – different – clinical conditions of skin layers
5. Chronic pathological skin conditions

Date of first enrolment
12/04/2024

Date of final enrolment
23/08/2024

Locations

Countries of recruitment
Bulgaria

Romania

Study participating centre
Syncro MD Medical Center
Bloc Alphaville Arena, Corp 3, Str. Stadionului 16
Brașov
Romania
500064

Study participating centre
AIDE-SANTE SRL
21 Rm. Valcea Street
Bucharest
Romania
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Study participating centre
Medical Center Prolet EOOD
25 Olimpi Panov Str., fl. 2
Ruse
Bulgaria
7000

Sponsor information

Organisation
Noventure S.L.

Funder(s)

Funder type
Industry

Funder Name
Noventure S.L.

Results and Publications

Individual participant data (IPD) sharing plan
Individual Participant Data (IPD) will be shared but only in anonymized form to protect participant privacy. The datasets generated during and/or analysed during the current study will be available upon request from the main contact person, based on the purpose of processing.

IPD sharing plan summary
Available on request