

# Bioelectric dressing in the treatment of chronic wounds

<b>Submission date</b> 26/07/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 07/09/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/11/2020	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Pressure ulcers (also known as pressure sores or bedsores) are injuries to the skin and underlying tissue, primarily caused by prolonged pressure on the skin. They can happen to anyone, but usually affect people confined to bed or who sit in a chair or wheelchair for long periods of time. In recent years, bioelectric dressings (WED) have been introduced to treat wounds in which electrochemical reactions are used to promote wound healing. The aim of the study is the impact assessment of the Procellera dressing (from Vomarix Wound Care Inc.; USA)

### Who can participate?

Men and women aged over 18 who have had an ischemic stroke or spinal cord injury and who suffer from grade II - IV pressure ulcers in the trunk, hip and lower limbs

### What does the study involve?

Participants will be randomly allocated to receive Procellera Antimicrobial Wound Dressing (from Vomarix Wound Care Inc.; USA), or treated with methods recommended by EPUAP (European Pressure Ulcer Advisory Panel), dressings will be changed every 2 days for 6 weeks.

### What are the possible benefits and risks of participating?

Participants may benefit from access to modern treatment, getting better treatment results and faster wound healing. Risks include allergic reactions to the applied treatment.

### Where is the study run from?

Academy of Physical Education in Katowice (Poland)

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

February 2019 to September 2022

### Who is funding the study?

Academy of Physical Education in Katowice (Poland)

Who is the main contact?

Ewa Kucio

ewakucio@poczta.fm

## Contact information

### Type(s)

Scientific

### Contact name

Dr Ewa Kucio

### ORCID ID

<http://orcid.org/0000-0003-1726-5518>

### Contact details

Mikołowska 72 A

Katowice

Poland

40-065

+48 (0)692704858

ewakucio@poczta.fm

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

5/2019

## Study information

### Scientific Title

The influence of bioelectric dressing on the healing rate of chronic wounds (pressure ulcers II-IV) and selected cytokines and growth factors in patients after ischemic stroke or spinal cord injury

### Acronym

BWT

### Study objectives

Bioelectric dressing therapy has better effects than standard dressing on the healing rate of chronic wounds and contributes to the reduction of pro-inflammatory cytokines and growth factors in patients after ischemic stroke or spinal cord injury

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 14/11/2019, Research Ethics Committee of the Academy of Physical Education in Katowice (ul. Mikolowska 72, 40-065 Katowice, Poland; +48 (0)322075152; a.smykla@awf.katowice.pl), ref: 5/2019

### **Study design**

Single-centre interventional randomized control trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Community

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

### **Health condition(s) or problem(s) studied**

Chronic wounds

### **Interventions**

The study will cover 60 patients with grade II - IV pressure ulcers after the central nervous system damage (ischemic stroke or spinal cord injury) hospitalized in the Department of Neurological Rehabilitation of the Upper Silesian Rehabilitation Center "REPTY" in Tarnowskie Góry.

Pressure ulcers will be classified on the basis of the four-level National Pressure Ulcer Advisory Panel (NPUAP) scale, according to which: in grade II pressure ulcers, there is a partial loss of dermis thickness. In grade IV, full thickness of skin is lost. Patients who develop leukocytosis will also be given antibiotics according to the antibiogram obtained from the wound swab culture. All immobilized patients will receive standard enoxyparin.

Patients referred for the study (or their legal guardians) will be informed in writing about the possibility of participating in the study and about the purpose and course of research. Patients

(or caregivers) will also be informed about the possibility of resigning from the study at each of its stages without giving a reason. Resignation from the study will not affect the further treatment of the patient.

After agreeing to participate in the study, patients will be divided randomly into two groups. Before starting the study, the Supervisor will prepare 60 (opaque) envelopes and 60 sheets with group symbols - 30 sheets will be marked with the symbol A and 30 sheets with the symbol B. The letter A will mean a control group, the letter B - an experimental group. Then the envelopes and sheets will be forwarded to a person not involved in the examination, who will put one sheet in the envelope and will seal the envelopes. Then this person will randomly number envelopes from 1 to 60 and give them to the Research Supervisor. After qualifying the patient for the study, the Research Supervisor will open another envelope and will direct the patient to the group based on the symbol in the envelope.

Patients qualified for the study will be randomly assigned to one of two groups:

1. Experimental group – 30 people, pressure ulcers will be treated with Procultura Antimicrobial Wound Dressing (from Vomed Wound Care Inc.; USA) and dressings will be changed every 2 days.

2. Control group – 30 people, pressure ulcers will be treated with methods recommended by EPUAP (European Pressure Ulcer Advisory Panel) - specialized dressings will be selected depending on the wound-healing phase, the presence of infection and the amount of wound secretions. In cases of clean and granulation pressure ulcers, hydrocolloid dressings and polyurethane foams will be used. In cases of pressure ulcers covered with fluid necrosis and characterized by a large amount of secretions, hydrogel and alginate dressings will be used. The dressings will be changed every two days. The duration of the experimental treatment will be 6 weeks.

Before starting the experiment and after 6 weeks of treatment blood samples will be taken for tests such as morphology, electrolyte levels (sodium, potassium), creatinine, total protein, total cholesterol and transaminase activity.

Before, in the first, second, fourth and six weeks of the study will be assessed:

1. Clinical progressions of pressure ulcers healing. Clinical advances in pressure ulcers healing will be assessed on the basis of changes in the pressure ulcers surface area (cm<sup>2</sup>). The surface area of pressure ulcers will be measured by planimetry immediately before the start of treatment and then after the end of each of the 6 consecutive treatment weeks. If the pressure ulcer heals before the end of the 6th week, the healing date will be recorded. Firstly, contours of pressure ulcers will be outlined with a waterproof marker on a transparent, soft foil, which is placed directly on the pressure ulcer. Next, the outline of pressure ulcer is transferred to a transparent, rigid foil and using a planimeter the loss surface area will be measured. The planimeter will be connected to a computer containing special C-GEO software enabling the calculating of the pressure ulcers surface area and data storage.

2. Evaluation of blood perfusion in the cutaneous vessels at the edges of pressure ulcers. Evaluation of blood perfusion in cutaneous vessels will be carried out by a non-invasive technique using laser Doppler flowmetry. Blood flow will be measured at the edges of pressure ulcers. In cases of pressure ulcers, whose surface area will be <20 cm<sup>2</sup> blood perfusion will be measured at four opposite points around the wound (taking the head as 12 o'clock on the clock face - the probes were fixed in the clockwise position at 12, 3, 6 and 9). In cases of pressure ulcers with a surface area larger than 20 cm<sup>2</sup> another measuring point will be added for each additional 5 cm<sup>2</sup>. Under the measuring probe, the skin temperature will be kept constant at 33 degrees C. The measurements will be carried out in a room with a temperature not lower than 21°C. Blood flow will be measured immediately before the start of treatment and then after 1,

2, 4 and 6 weeks of therapy.

3. Assessment of pro-inflammatory cytokines: tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ), interleukin 1 (IL-1), interleukin 6 (IL-6) and anti-inflammatory interleukin 10 (IL-10) and growth factors: transforming growth factor beta (TGF- $\beta$ ), insulin-like growth factor type 1 (IGF-1), fibroblast growth factor (FGF), epidermal growth factor (EGF), blood vascular endothelial growth factor (VEGF) will be evaluated before and after the 1, 2, 4 and 6 weeks of the experiment. To determine the concentration of cytokines and growth factors, 5 ml of venous blood will be taken from the ulnar vein each time. The collected blood serum will be centrifuged and stored at -80°C until the day of cytokines assay. Cytokines and growth factors in serum will be determined by the Enzyme-linked immunosorbent assay (ELISA).

4. The concentration of cytokines and growth factors in the liquid from the wound edges will be performed before and after 1, 2, 4 and 6 weeks of treatment

5. Expression of genes responsible for cytokine synthesis (TNF- $\alpha$ , IL-1, IL-6 and IL-10) and growth factors (TGF- $\beta$ , IGF-1, FGF, EGF and VEGF)

From each patient (included in the experiment), before and after 1, 2, 4 and 6 weeks of treatment, a biopsy will be taken from the wound area in which mRNA responsible for biosynthesis of the following factors will be determined: proinflammatory cytokines (TNF- $\alpha$ , IL-1 and IL-6) and anti-inflammatory (IL-10) and growth factors: transforming growth factor beta (TGF- $\beta$ ), insulin-like growth factor type 1 (IGF-1), fibroblast growth factor (FGF), epidermal growth factor (EGF), vascular endothelial growth factor (VEGF). The biopsy after completion of the study will not be taken if the pressure ulcer heals or if its surface area will be less than 1 cm<sup>2</sup>.

## **Intervention Type**

Other

## **Primary outcome measure**

Healing rate of chronic wounds (pressure ulcers II-IV). The surface area of pressure ulcers will be measured by planimetry immediately before the start of treatment and then after the end of each of the 6 consecutive treatment weeks.

## **Secondary outcome measures**

1. Blood flow on the edges of chronic wounds will be measured by a non-invasive technique using laser Doppler flowmetry immediately before the start of treatment and then after 1, 2, 4 and 6 weeks of therapy

2. Concentration of pro-inflammatory cytokines (TNF- $\alpha$ , IL-1 and IL-6) and anti-inflammatory (IL-10) in the blood and liquid collected from the wound edges will be determined by the Enzyme-linked immunosorbent assay (ELISA) before and after 1, 2, 4 and 6 weeks of the experiment

3. Concentration of growth factors: transforming growth factor beta (TGF- $\beta$ ), insulin-like growth factor type 1 (IGF-1), fibroblast growth factor (FGF), epidermal growth factor (EGF), vascular endothelial growth factor (VEGF) in blood and in liquid from the wounds' edges will be evaluated by the Enzyme-linked immunosorbent assay (ELISA) before and after 1, 2, 4 and 6 weeks of the experiment

4. Expression of genes responsible for cytokine synthesis (TNF- $\alpha$ , IL-1, IL-6 and IL-10) and growth factors (TGF- $\beta$ , IGF-1, FGF, EGF and VEGF) in the wound area of the pressure ulcer will be evaluated by PCR before and after 1, 2, 4 and 6 weeks of the experiment

## **Overall study start date**

01/02/2019

## **Completion date**

30/09/2022

# Eligibility

## Key inclusion criteria

1. Male and female older than 18 years after stroke or spinal cord injury, with grade II-IV pressure ulcers in the trunk, hip girdle and lower limbs, who have a high risk of pressure ulcers (the Norton scale <14 points; the Waterlow scale >15 points)
2. Consent to participate in the study

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

60 (30 in each group)

## Key exclusion criteria

1. Lack of consent to participate in the study
2. Malignant neoplasms
3. Allergies to standard medicines
4. Occurrence of acute inflammatory symptoms within the pressure ulcer
5. Black necrosis occurring within the pressure ulcer
6. Pressure ulcers qualifying for surgical treatment
7. Pressure ulcers occur on the lower legs or feet in patients with acute and chronic venous insufficiency and diabetes
8. Pressure ulcers with a surface area less than 0.5 cm<sup>2</sup>
9. Significant malnutrition (BMI <18 kg/m<sup>2</sup>)
10. The low concentration of protein in blood (<60 g/l)
11. Decompensated diabetes (HBA1C >7%)

## Date of first enrolment

01/09/2021

## Date of final enrolment

01/08/2022

# Locations

## Countries of recruitment

Poland

**Study participating centre**

**Jerzy Kukuczka Academy of Physical Education in Katowice**

Department of Fundamental Physiotherapy

Katowice

Poland

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**Study participating centre**

**Jerzy Kukuczka Academy of Physical Education in Katowice**

Department of Physiotherapy in Internal Diseases

Katowice

Poland

-

**Study participating centre**

**Upper Silesian Rehabilitation Center "REPTY" in Tarnowskie Góry**

Tarnowskie Góry

Poland

-

## **Sponsor information**

**Organisation**

Academy of Physical Education in Katowice

**Sponsor details**

Mikołowska 72 A

Katowice

Poland

40-065

+48 (0)32 207 51 10

rektorat@awf.katowice.pl

**Sponsor type**

University/education

**Website**

<http://www.awf.katowice.pl>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

Academy of Physical Education in Katowice

**Funder Name**

Vomaris Wound Care

## **Results and Publications**

**Publication and dissemination plan**

Publication in a high-impact peer-reviewed journal.

**Intention to publish date**

01/12/2022

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.

**IPD sharing plan summary**

Stored in repository