ISRCTN56600087 https://doi.org/10.1186/ISRCTN56600087

Bioelectric dressing in the treatment of chronic wounds

Submission date	Recruitment status	[X] Prospectively registered
26/07/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/09/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
19/11/2020	Skin and Connective Tissue Diseases	[_] 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 Vomaris 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 Vomaris 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 then 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 participiant 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 Procellera Antimicrobial Wound Dressing (from Vomaris 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 (cm2). 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^2 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^2 another measuring point will be added for each additional 5 cm2. 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 21OC. 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-α (TNF-α), interleukin 1 (IL-1), interleukin 6 (IL-6) and anti-inflammatory interleukin 10 (IL-10) and growth factors: transforming growth factor beta (TGF-β), 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 -80oC 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-α, IL-1, IL-6 and IL-10) and growth factors (TGF-β, 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-α, IL-1 and IL-6) and anti-inflammatory (IL-10) and growth factors: transforming growth factor beta (TGF-β), 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^2.

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-α, 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-β), 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-α, IL-1, IL-6 and IL-10) and growth factors (TGF-β, 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^2
9. Significant malnutrition (BMI <18 kg/m^2)
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
-

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