BodStim TM Klotho and Follistatin Protein Expression Controlled Muscle Stimulation and Bicycling Combined for Muscle Strength and Elasticity Stretch Enhancement in Post ICU Rehabilitation Patients

ClinicalTrials.gov Identifier:

Recruitment Status : Not Yet Enrolling
First Posted : June 2nd, 2022
Last Update Posted : June 2nd, 2022

Sponsor:
Leonhardt Ventures LLC, 1 Kent Court, Mission Viejo, CA 92694 on behalf of BodStim by BioLeonhardt Whole Body and Lionheart Health, Inc.
Information provided by (Responsible Party):
Leonhardt Ventures LLC

- **Study Details**

Study Description

Brief Summary:

The **BodStim TM bioelectric stimulation suit developed in collaboration with HTM Electronics and Weimspro is unique in that in addition to standard muscle contraction stimulation signals it also includes proprietary bioelectric signaling sequences for controlling the release of klotho and follistatin two well established muscle regeneration and injury recovery proteins.**
Early mobilization (from the first day if possible), first passive and then passive and active, is recommended for critically ill patients in whom it reduces the duration of mechanical ventilation, the length of hospital stay, improves functional status, **muscle** strength and quality of life after hospital discharge. The early addition of leg bicycling on a cyclo-ergometer is now part of common practice in the ICU and in post ICU rehabilitation clinics. It can preserve or improve **muscle** strength and further increase the beneficial effects of early mobilization. Electrical **muscle stimulation** of the quadriceps, is practiced in some intensive care units, and it should, in theory, also through an improvement of **muscle** strength, increase the beneficial effects of early mobilization.
We hypothesized that early quadriceps, abdominal and other muscles electrical **stimulation** and early post ICU discharge work on a cyclo-ergometer associated with a standard protocol of early passive/active mobilization immediately

after ICU discharge may improve **muscle** function and reduce the duration the number of readmissions and improve the quality of life (more rapidly get them back to a full normal quality of life) including mental well being of recovering out of ICU patients, as compared to a conventional protocol of early passive/active mobilization.

Condition or disease	Intervention/treatment	Phase
ICU-acquired **Muscle** Weakness	Other: BodStim electrical **stimulation** and early leg bicycling added to early standard rehabilitation 1 hour 3X a week for 8 weeks	Pilot

Study Design

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	30 participants
Allocation:	Non-Randomized
Intervention Model:	All receive stimulation and 3 bicycle exercise 1 hour 3X a week
Masking:	Single (Outcomes Assessor)
Primary Purpose:	Prevention and recovery
Official Title:	Early Post ICU Rehabilitation Combining Daily Electrical **Muscle Stimulation** and Early Bedside Cycling Exercise, Compared to Early Standard Rehabilitation. A Randomized, Assessor-blinded, Single-center Study in Intensive Care Patients.
Actual Study Start Date :	August 15, 2022
Actual Primary Completion Date :	March 15th, 2022
Actual Study Completion Date :	TBD

Resource links provided by the National Library of Medicine
MedlinePlus related topics: Rehabilitation
U.S. FDA Resources

Arms and Interventions

Arm	Intervention/treatment
Active Intervention: Electrical **muscle stimulation** and bicycling Patients will undergo early electrical **stimulation** of the quadriceps and other muscles via the BodStim TM bioelectric electrode suit 1 hour 3X a week for 8 weeks and with leg bicycling for half of the duration time or 30 minutes in addition to routine care (which comprises early standard mobilization). So for each treatment session **the patient will wear the BodStim bioelectric suit for 1 hour and will alternate during that 1 hour between 15 minutes of resting state stimulation, 15 minutes of bicycling with stimulation, 15 minutes of rest state stimulation and final 15 minutes of stimulation while actively pedaling the bicycle.** Klotho blood sample will be taken before the first treatment session begins to establish a baseline and once more at the end of the final 15 minutes of stimulation and bicycling at 8 weeks.	Other: Early electrical **stimulation** and early leg bicycling added to early standard rehabilitation

Outcome Measures

Primary Outcome Measures :

1. **Global muscle strength** assessed by the MRC (Medical research Council, 1978) score upon enrollment in study before any treatment sessions have begun.
Global muscle strength assessed by the MRC (Medical research Council, 1978) score after 8 weeks of BodStim TM stimulation and bicycling combination treatments. This evaluation will be conducted by a physiotherapist.
2. Assessment of **muscle stretch enhancement via** head to knee hand to toes reach stretch change recorded by digital photography means.
3. **Circulating Klotho levels** via a blood sample and test before and after full 8 week treatment regime. Latter test immediately following last bicycling + BodStim TM stimulation treatment session at 8 weeks.

Secondary Outcome Measures :

Changes in thickness of the rectus femoris muscle of each thigh from baseline to 8 weeks treatment sessions completion.

- Changes in thickness of the rectus femoris **muscle** of each thigh, as measured by ultrasound imaging, between inclusion and 8 weeks treatment sessions completion.
- **Mental well being** - Professional assessment of depression levels mental health by qualified personnel. (Time Frame: Enrollment baseline compared to after 8 weeks of treatment)
- Change in Hamilton **Depression** Rating Scale scores (17-item version) [Time Frame: Weeks 0,8]
- Clinician-administered **Anxiety** assessment scale. Score range = 0 - 30 (higher scores mean worse outcome).

1. **Quality of Life Changes** (Time Frame: Enrollment baseline compared to 8 weeks after treatment sessions]
- Quality of life assessed by the SF-36 questionnaire.

Eligibility Criteria

Information from the National Library of Medicine
Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria
Inclusion Criteria:

- age over 18 yrs
- expected length of stay in the ICU higher than 72 hours
- motor autonomy sufficient for independent ambulation (ass assessed by patient/family/familial practitioner interview

Exclusion Criteria:

- Opposition expressed by the patient, his/her legal representative or a member of his/her family
- Pregnant woman
- Resuscitated cardiac arrest before inclusion
- Patient carrying a pacemaker or an implantable defibrillator
- Patient under extracorporeal membrane oxygenation
- Severe acute cerebral disease requiring deep sedation
- Brain death
- Guillain-Barré syndrome

- Myasthenia gravis
- Known Dementia than can affect the main endpoint assessment
- Deep venous thrombosis or pulmonary embolism treated for less than 48 hours, or floating clot in femoral, iliac of inferior vena cava veins
- Unstable traumatic injuries of the spine
- Severe skin disease or surgical reasons that either prevent performing electrostimulation or bicycling in the next 2 days, or prevent patient's verticalization or transfer to chair in the next 5 days
- Amputation of a lower limb at the trans-metatarsal level or higher
- Inclusion in another interventional study with muscle strength assessment as the primary endpoint
- Moribund patient

Contacts and Locations

Information from the National Library of Medicine
To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.
Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02185989***

Locations
Santa Casa Hospital Rehabilitation Unit Dr. Rodrigo Plentz, Porto Alegre, Brazil
Sponsors and Collaborators
Leonhardt Ventures LLC
Investigators

Principal Investigator:	Dr. Rodrigo Plentz, Santa Casa Hospital, Porto Alegre, Brazil
	Dr. Joci Schardong, Santa Casa Hospital, Port Alegre, Brazil
	Dr. Cristiane Carboni, Porto Alegre, Brazil

More Information

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):
Fossat G, Baudin F, Courtes L, Bobet S, Dupont A, Bretagnol A, Benzekri-Lefèvre D, Kamel T, Muller G, Bercault N, Barbier F, Runge I, Nay MA, Skarzynski M, Mathonnet A, Boulain T. Effect of In-Bed Leg Cycling and Electrical Stimulation of the Quadriceps on Global Muscle Strength in Critically Ill Adults: A Randomized Clinical Trial. JAMA. 2018 Jul 24;320(4):368-378. doi: 10.1001/jama.2018.9592.

Responsible Party: Leonhardt Ventures LLC

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Keywords provided by Centre Hospitalier Régional d'Orléans:

Critical Illness/*rehabilitation
Humans
*Intensive Care Units
Muscle Weakness/diagnosis/*etiology/physiopathology/prevention & control
Polyneuropathies/diagnosis/*etiology/physiopathology
Mental well being - depression

Additional relevant MeSH terms:

Muscle Weakness
Paresis
Muscular Diseases
Musculoskeletal Diseases