H-47781- EFFECTIVENESS OF LOWER EXTREMITY ELECTRICAL STIMULATION THERAPY IN THE TREATMENT OF LOWER EXTREMITY CRITICAL ILLNESS MYOPATHY AND NEUROPATHY IN PATIENTS WITH SEVERE COVID-19

Concise and Focused Presentation

You are being asked to participate in a voluntary research study. The purpose of this study is to see if Electrical Stimulation will benefit a long stay in the ICU. In this study we will place a low risk device to measure the strength of the legs and give Electrical stimulation to help reduce pain and add blood circulation and muscle movement. No research procedures will take place before signing the consent form. Your participation in this study will be voluntary. There is minimal risks and you may benefit from this study by not losing strength (muscle loss in your legs) and less pain in your legs. You do not have to participate in this study and can continue to receive your normal care.
Prolonged ICU stay can cause side effects such as muscle loss, weakness and pain on the legs, specially in patients with COVID-19. Electrical stimulation has shown to improve blood circulation, decrease pain, and prevent muscle loss in patients with leg diseases. We purpose the daily use of electrical stimulation to address the side effects on the legs caused by prolonged ICU stay in patients with COVID-19. During the first visit, the research team will test the status of the leg muscles with a simple tool which records muscle activity while performing electrical stimulation with a low risk device pads will be replaced and device will be placed in a plastic bag and sanitized after each use.Then, electrical stimulation therapy will be provided by the nursing staff every day during a period of 4 weeks or until the patient heals, whichever comes first. Finally on the day of the patient's discharge from the hospital, the research team will test the status of the legs again, in order to examine the efficacy of daily use of electrical stimulation for patients with COVID-19 in the ICU.
You will be provided his/her own Electrical stimulation device during the complete study period, and it will not be re-used or recycled for other patients' use. For Yourself and research staff safety, sanitation and monitoring of the device will be performed everyday before and after therapy to reduce any risks.

Background

You are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part in the study.

Patients with COVID-19 admitted to the Intensive Care Unit could be at risk of losing their muscle strength from being unable to move for a long period of time during their stay, developing pain can cause weakness to the legs. Due to ICU-acquired weakness, Physical therapy (PT) programs are often required to prevent or recover. However, PT is often impractical for COVID-19 patients because it can be risky to health providers or because the patients are unable to perform PT tasks (e.g., the patient is not awake or has severe mobility limitations). To address this issue, we suggest the daily use of electrical stimulation (EE) therapy provided to the legs, as an alternative therapy to maintain muscle activity. We think that implementation of EE will improve myopathy among COVID-19 patients by preventing muscle leg loss and weakness. However, these devices have not been used before for purpose of managing COVID-19 side effects like the purpose of this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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Purpose

The purpose of this pilot study is to examine effectiveness of daily use of electrical stimulation therapy to address side effects on the legs caused by prolonged ICU stay in patients with COVID-19.

Procedures

The research will be conducted at the following location(s):
Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC).

fWe will recruit 20 subjects with severe COVID-19 infection in Intensive Care Unit. You will receive daily electrical stimulation on both of your the legs up to 1 hour in order to decrease muscle loss, pain, and weakness, which are complications of prolonged ICU stay.

As electrical stimulation may offer an alternative treatment to reduce pain and improve blood flow, it could also have positive effects to improve mobility and balance by reducing the loss of sensation in your legs, which has also shown to be a side effect of prolonged ICU stay.

We will assess incidence of leg numbness, muscle weakness, and incident of Myopathy at ICU discharge or 4 weeks, whichever comes first on both legs. We will use a a device that delivers minimal vibration to detect feeling and sensitivity. (Vibratory perception threshold) test. We will use a scale to test the strength by a pulling motion and detect the weakness by a tool called Dynamo meter which evaluates muscle strength. Muscle loss will be evaluated by measuring the calf muscle circumference at first visit and discharge date in order to compare the thickness of the leg. Length of ICU stay and major adverse events (documented via electronic health record) will be tracked for planning of future studies. Both extremities will have all measurements and electrical stimulation therapy at baseline and during the study period. Daily treatment will performed up to 3 times per day, but no more than 1 hour in total.

The researchers will take digital photographs /videos of both of your legs throughout the study. This is done using a special digital camera for visual images and blood flow detection. This method is non invasive and does not cause any harm to you. **We will blur your face out in the photographs/videos. While we do all our efforts to mask your face in some cases (for example.
journal policy) this may not be practical. We will only use videos and photos of you for scientific presentations or scientific publications.

Initial your decision below.
____I agree to have my photographs/videotape presented in scientific presentation or scientific publication
____I do NOT agree to have my photographs/videotape presented in scientific presentation or scientific publication
If you are eligible, the research personnel would like to contact you in the future for participation in other research studies. You are not required to participate in these studies and your medical care or involvement with the current research study will in no way be affected if you choose not to participate . You may ask us to stop contacting you at any time.

_____I agree to be contacted for future research studies
_____I do not agree to be contacted for future research studies.
Please provide below your Emergency contact information:
Contact name:_____
Relationship: _____
Phone number:_____
Please note that the research staff may contact you for any study related questions or concerns during your participation of the study.
If you are a student or employee, note that your participation will NOT affect your academic position or employment. You may also refuse to participate without any penalty.

Clinically Relevant Research Results

The results generated from this research study are not expected to have any clinical relevance to you.

Sharing and Future Research Studies with Identifiable Private Information

Your identifiable private information or identifiable biospecimens collected as part of this research, even if the identifiers are removed, will not be used or distributed for future research studies.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Specific information concerning alcohol abuse
- Specific information concerning drug abuse
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Billing or financial records
- Photographs, videotapes, and/or audiotapes of you

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, and Baylor St. Luke's Medical Center (BSLMC).

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. However, your health information that is necessary to your care will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) maintain in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC) to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific institution where you are being enrolled into this research study which are: Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC).

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine, and Baylor St. Luke's Medical Center (BSLMC) may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Bijan Najafi, PhD

7200 Cambridge Street, Room B01.529

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

This study brings no more than minimal risk to subjects as it only involves a non-invasive device. There are some risks associated with lack of comfort from Electrical Stimulation, skin allergy to the Electrical Stimulation sticky patches that are used for delivering Electrical Stimulation therapy, risk associated with electrical mal-function of Electrical Stimulation, and other unknown risks. All Electrical Stimulation devices will be checked before any use to minimize the risk associated with electrical malfunction. All Electrical Stimulation devices are FDA approved for the purpose of pain reduction. The device has provided pain relief in previous studies and their participation may help researchers identify the impact of a disorder on mobility performance as well as the changes of mobility during an intervention. This device is an investigational device. The study device and technology are non-invasive, non-toxic and non-ionizing. The potential risks are minimal. However, like any battery powered systems, there is a minimum risk of sensor malfunctioning.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits

The benefits of participating in this study may be: There is a potential benefit or prevention or improvement in this study, the device has been proven to reduce pain, activate muscle mass, and increase blood flow. However, the proposed treatment may assist in preventing or improving ICU-acquired Weakness because of prolonged ICU stay. In addition, the participation in this study may help the investigators to better understand how COVID-19 may impact Myopathy and Neuropathy caused by prolonged ICU-stay. Therefore, the research team will investigate how this therapy helps COVID-19 patients to recover from prolonged ICU-stay .

. However, you may receive no benefit from participating.

Alternatives

You may choose to not participate in this study.

Investigator Withdrawal of Subject from a Study

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city, if you are not being provided the Electrical Stimulation therapy, or if you have a serious reaction to Electrical Stimulation therapy) or because the entire study is stopped. The sponsor, investigator, Food and Drug Administration, or Institutional Review Board may stop the study at any time.

Subject Costs and Payments

You will not be asked to pay any costs related to this research.

You will not be paid for taking part in this study.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, BIJAN NAJAFI, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: BIJAN NAJAFI at 713 7987536 during the day and MARIA NOUN at 713-798-7538 after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Legally Authorized Representative - Adult	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date