H-52968- NEUROMODULATION FOR PREVENTION OF INTENSIVE CARE UNIT ACQUIRED WEAKNESS AND POST INTENSIVE CARE SYNDROME - PROOF OF CONCEPT RANDOMIZED CONTROLLED TRIAL

Concise and Focused Presentation

Prolonged hospital stay and low mobility can cause side effects such as muscle , nerve, and circulation damage on the legs, especially in patients who are admitted to the intensive care unit. Neuromodulation is a therapy that consists in stimulating the muscles with electricity in order to improve blood circulation, decrease pain, and prevent weakness. The intensity of the electricity is very low and does not cause pain or harm. This therapy has shown to be safe and helpful for people with leg diseases. Therefore, we propose the daily use of neuromodulation therapy to prevent the side effects on your legs caused by prolonged hospital stay in the intensive care unit.

We propose the daily use of neuromodulation therapy for up to 4 weeks during your hospital stay to address the side effects on the legs caused by intensive care unit admission . During the first visit, the research team will test the status of your leg muscles with a simple non-invasive tool which records muscle activity while performing neuromodulation therapy. Low risk device pads will be attached to your calf muscles during the stimulation. The research team will also measure the muscles of your legs with a non-invasive tool and will evaluate the blood circulation of your legs with a simple picture taken with a non-invasive camera that detects circulation from the skin. Then, will you be selected at random to receive either a commercial (active) device or a placebo device to receive daily neuromodulation therapy for up to 4 weeks. You will be provided your own neuromodulation device and device pads during the complete study period, and it will not be re-used or recycled for other patients' use. Neuromodulation therapy can be done at any time of the day as long as it is for 1 hour.

At 3 and 7 days, the research team will test the status of the legs again, in order to examine the effect of daily use of neuromodulation therapy at the intensive care unit. Then, this will be done weekly after completing 4 weeks. If you are discharged from the hospital before 4 weeks, the research staff will test the status of your legs before you leave the hospital. After one month from hospital discharge, the research team may contact you via telephone call to fill out questionnaires related to your current quality of life and physical activity.

This study brings no more than minimal risk to you. However, there are some risks associated with discomfort from neuromodulation therapy, like skin allergy to the neuromodulation sticky patches that are used for delivering neuromodulation therapy, risk associated with electrical malfunction of neuromodulation, and other unknown risks. Each of the neuromodulation devices will be checked before any use to minimize the risk associated with neuromodulation.

The neuromodulation device used in this study is FDA-cleared for pain relief and pain management. However, this study plans to examine this device's impact on muscular characteristics and mobility performance during and after an intervention. Thus, this device's use is investigational for the purpose of this study. The device and electrical pads 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.

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 recovering from hospital-acquired weakness because of prolonged hospital stay. In addition, the participation in this study may help the investigators to better understand the impact muscle damage caused by prolonged hospital stay. Therefore, the research team will investigate how this therapy helps ICU patients to recover from adverse events of hospital stay and immobilization. Nonetheless, you may choose to not participate in this study.

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 admitted to the intensive care unit could be at risk of getting weakness, have nerve and/or circulation damage on their legs from being unable to move for a long period of time during their stay. Especially, patients that need intubation to breath are at higher risk to developing these complications because they are not awake. To prevent leg complications, neuromodulation therapy provided to the legs is an alternative treatment to keep your muscles active and prevent muscle leg loss, weakness, nerve and circulation issues.

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.

Purpose

The purpose of this pilot study is to see if daily use of neuromodulation therapy works to prevent side effects related to the legs, such a low mobility, caused by intensive care unit stay.

Procedures

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

We will recruit 40 patients that have been admitted to the intensive care unit. The patients who are recruited will be randomly assigned to either a treatment or placebo group. If you are assigned to the treatment group, you will receive an active device that delivers low-intensity electrical signals to your legs during your hospital stay. Daily, treatment will be performed for no more than 1 hour. If you are assigned to the control group, you will receive a placebo device that delivers very little electrical signals and does not stimulate your leg muscle. You and your clinician will not be told which group you were assigned. Regardless of which group you are assigned to, during electrical stimulation therapy sessions, low-risk, adhesive pads will be attached to your calf muscles. A wire will then be used to connect the pads to the stimulation device.

Whether you are assigned to the treatment or placebo group, you will be seen at 3 days, and then every week after that until completing 4 weeks or until you are discharged from the hospital, whichever comes first. In each visit we will evaluate your leg muscle activation, circulation, and nerve function using the procedures outlined below.

During the first (baseline) visit, the research team will complete the following assessments:
1. To evaluate your muscle activity: we will use a sensor and attach it to your calf while performing 5 minutes of electrical stimulation with an active device (regardless of which group you were assigned).
2. To evaluate your muscle volume: we will use an ultrasound probe and place it over your calf, this probe is non-invasive and does not elicit pain or irritation.
3. To assess nerve status: we will use a non-invasive device placed on your calf that detects your nerve activity.
4. To assess your leg circulation: we will take pictures of your foot with a specialized camera that detects oxygen from your skin. 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

We will conduct the above assessments for both of your legs at baseline and during each follow-up study visit. In the final visit, when you are awake, we will evaluate your leg strength by asking you to flex your ankle with a band around it. We will also collect the data from medical records regarding the regular blood work you have had during your stay. All visits will take approximately 30 minutes.

During the study period, you will be provided your own electrical stimulation device (either active or placebo) and adhesive pads. It will not be re-used or recycled for other patients' use.

Lastly, after 1 month has passed since your discharge from the hospital, the research staff will reach you via telephone call to perform questionnaires related to your daily activity and ability to perform activities without help, community engagement, and anxiety. The questionnaires are not mandatory if you wish to not to be contacted.

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 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.
- Demographic information (name, D.O.B., age, gender, race, etc.)
- 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).

The data coordinating center will have access to the research records including your health information.

A Data and Safety Monitoring Board will have access to the research records including your health information.

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, data coordinating center, Data and Safety Monitoring Board, 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: 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 neuromodulation therapy, like skin allergy to the neuromodulation sticky patches that are used for delivering electrical stimulation therapy, risk associated with electrical malfunction of neuromodulation, and other unknown risks. Each of the neuromodulation devices will be checked before any use to minimize the risk associated with neuromodulation.

The neuromodulation device used in this study is FDA-cleared for pain relief and pain management. However, this study plans to examine this device's impact on muscular characteristics and mobility performance during and after an intervention. Thus, this device's use is investigational for the purpose of this study. The device and electrical pads 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 recovering from hospital-acquired weakness because of prolonged hospital stay. In addition, the participation in this study may help the investigators to better understand the impact muscle damage caused by prolonged hospital stay. Therefore, the research team will investigate how this therapy helps ICU patients to recover from adverse events of hospital stay and immobilization. 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 do not take your study medication, or if you have a serious reaction to your study medication) 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 7137987536 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