Consent to Participate in a Research Study

TITLE: The impact of lower extremity weight-bearing leg exercise during the pre-ambulation phase of individuals undergoing extracorporeal membrane oxygenation (ECMO).

INVESTIGATORS:

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Fairview Health Services

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University of Minnesota
Program in Physical Therapy

You are invited to participate in a research study looking at physical therapy participation undergoing "extracorporeal membrane oxygenation" or ECMO, which is a form of life support. You were selected as a possible participant because you are between the ages of 18 and 70 years of age and are able to move while undergoing this form of life support. Your participation is completely voluntary.

To allow you to make an informed decision as to whether or not you want to take part in this research study, this document describes the purpose of the study, your rights and obligations, and the possible benefits and risks of participating in the study. Please take time to read the following information carefully. Feel free to communicate with your doctor(s), family, or friends before deciding if you would like to take part. Please ask your study doctor if there is anything that is not clear or if you would like more information. If you have decided that you want to take part, you will be asked to sign this consent form. You will be given a copy of this form to keep, and the original will stay in a study file.

This study is being conducted in party, by Eric Andersen, PT, DPT who is a staff physical therapist that works in the hospital you are at.

Study Purpose

The purpose of this study is to see if using a machine that targets specific muscles in conjunction with getting out of bed and moving around in a safe manner while undergoing ECMO will change physical and functional outcomes. You will either be a part of the group that uses the machine or does not use the machine.

If any new information arises that may change your mind about participating in or continuing with the study, we will tell you about it.

Study Length

• If you agree to complete the entire study, you will be seen by a physical therapist and mobility team 5 days per week while you are undergoing ECMO treatment. Once ECMO treatment is complete, your study participation will be finished. However, you will still be seen by a physical therapist as tolerated to continue to progress your strength and function.

Participation Criteria

- Undergoing veno-venous ECMO – a form of life support that allows patients to move around
- Are able to follow 3/3 commands
- Are able to bear weight through both lower extremities
- Have no other medical reasons to not be able to get out of bed

Study Procedures

If you agree to participate in the study, you will be asked to do the following:

- Work with a physical therapist (and possibly an occupational therapist) along with a mobilization team of respiratory therapists and nurses to improve your strength and function while undergoing ECMO life support. Specifically you will perform these activities:
    - Utilize our ceiling lift system to sit at the edge of the bed and be moved into a chair
    - Sit at the edge of the bed without the assistance of a ceiling lift system
    - Begin to start standing and moving to a chair on your feet
    - Walk with the aide of a four-wheeled mobility cart
- If you are in the specific leg strengthening machine group, you will be assisted onto the machine utilizing a ceiling lift system while you are working on the above activities
- You will progress your function and strength with the goal of walking in the hallway
- All vital signs, ECMO specifications and ventilator specifications will be closely monitored throughout your participation

Risks of Study Participation

- Significant change in vital signs causing temporary or permanent damage
    - Although highly unlikely, this will be closely monitored with every movement
- Accidental ECMO or ventilator removal
    - Emergency situation and professionals will be in place to act accordingly if this happens

Discontinuation without Subject Consent

Under certain conditions, the study may be discontinued without your consent. If a condition arises that puts you at risk, we will stop the study immediately. This is for your safety.

Benefits of Study Participation

Improvement in your function may be seen while undergoing ECMO life support and carryover into your recovery from your entire health situation.

Alternatives to Study Participation
The alternative to participating in this study is to not participate or to withdraw from the study at any time after you have consented to participate.

Study Costs/Compensation
No cost to you as physical and occupational therapy consults are a part of your hospitalization and also "usual-care" in regards to effects of prolonged bedrest.

Research-Related Injury
In the event that this research activity results in an injury or if you feel that you have suffered a research-related injury, notify a member of the study staff immediately. Treatment will be available including first aid, emergency treatment, and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury and that you may be eligible for reimbursement of some medical care costs, let the study physicians know right away.

Confidentiality
The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Departments at the University with appropriate regulatory oversight may however, review your record for the study. In any publications or presentations, data will be de-identified and not include any information that would make it possible to identify you as a subject. Your record for the study may be reviewed by departments at the medical center with appropriate regulatory oversight. Your study participation and results may be included in your medical record but any other information will not. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide us with that permission.

Protected Health Information (PHI)
Your PHI created or received for the purposes of this study is protected under the federal regulation, known as HIPAA. Please refer to the attached HIPAA authorization for detail concerning the use of this information.

Voluntary Nature of the Study
Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University or Fairview. If you decide to participate, you are free to withdraw at any time without affecting those relationships. Compensation will be given at completion of the study visit(s).

Contact Information
If you have questions, do not hesitate to ask at any time. If you have questions later, you are encouraged to contact Eric Andersen, PT, DPT at (262) 391-6839 or Amanda Lalonde, PT, DPT at (612) 910-7363. You may also reach us at eander30@fairview.org or lalonde@umn.edu, respectively.

To share feedback privately about your research experience, including any concerns about the study, call the Research Participants Advocate Line: 612-625-1650 or give feedback online at

www.irb.umn.edu/report.html. You may also contact the Human Research Protection Program in writing at D528 Mayo, 420 Delaware St. Southeast, Minneapolis, Minnesota 55455.

Statement of Consent
I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Name of Subject (printed): _____ Date: _____

Signature of Subject_____ Date: _____

Person Obtaining Consent (printed): _____ Date: _____

Signature of Person Obtaining Consent: _____ Date: _____

**If third party interpreter is used as a witness for consent, please sign below*

Name of Witness (printed): _____ Date: _____

Signature of Witness: _____ Date: _____