Compression Wraps as adjuvant therapy in the management of acute systolic heart failure (CATAS-HF trial)

8/1/2019

- Informed Consent Form

NCT #: NCT04095416

	CONSENT TO PARTICIPATE IN A RESEARCH STUDY (HFH IRB form rev: 12/7/2018)	DATE: MRN: NAME:
	PROJECT TITLE: **Compression Wraps as adjuvant therapy in the management of acute systolic heart failure (CATAS-HF trial)**	

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1. INTRODUCTION

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when deciding whether or not to participate. More detailed information is provided after the box. No research activity is to be conducted until you have had an opportunity to review this consent form, ask any questions you may have, and sign this document.

Key Information for You to Consider

Voluntary Consent. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.

Purpose. The purpose of this research is to evaluate use of lower extremity compression wraps in treatment of patients with acute systolic heart failure.

Duration. It is expected that your participation will last for the duration of the hospitalization.

Procedures and Activities. You will be asked to wear compression wraps on both legs.

Risks. Some of the foreseeable risks or discomforts of your participation include leg pain while wearing the compression wraps. More detailed information can be found in the "*What Are The Risks, Discomforts, And Inconveniences Of The Study?*" section in the Consent Form.

Benefits. Some of the benefits that may be expected include improved leg swelling.

Alternatives. Participation is voluntary and the only alternative is to not take part in this research study.

2. DISCLOSURE OF POTENTIAL CONFLICT OF INTEREST

The investigator(s) in this study are also healthcare providers. They are interested in the knowledge to be gained from this study and are interested in your well-being. Investigators do not receive salary or other financial support from the study sponsors in exchange for conducting this study.

3. WHY IS THIS RESEARCH BEING DONE?

You have been asked to take part in a research study because you are being treated in the hospital for acute systolic heart failure. The purpose of this research study is to evaluate the efficacy of leg compression wraps in the treatment of acute systolic heart failure.

A total of 120 people will be enrolled at Henry Ford Health System (HFHS). This

study is sponsored by Henry Ford Health System.

As part of this study, you will be given ACE Compression Wraps. This device is approved by the FDA (U.S. Food and Drug Administration) for this purpose.

4. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

During your hospitalization, in addition to standard medical care, you will receive ACE Compression Wraps to be worn on both legs for the entirety of the hospital stay, as tolerated. The wraps are completely voluntary, but participation in the study requires they be worn for as long as possibly tolerated, with removal for hygiene and comfort purposes only as needed, with immediate re- application. The remainder of your hospital course will remain unchanged. You will also receive information and education on lower extremity compression wraps. The data collected from your hospital stay will be include: medications used, total length of hospital stay, daily weights, and laboratory values (electrolytes, BNP, creatinine, intake and output). This data will then be used to assess the use of compression wraps in managing patients with the same diagnosis in the hospital.

FOR RANDOMIZED/BLINDED STUDIES: There will be two groups in the study. You will be randomized into one of the study groups described below. Randomization means that the group you are assigned to will be chosen by chance, like flipping a coin. A computer program will place you in one of the study groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in either one of the two groups.

If you are in group 1 (often called "Arm A"), you will receive standard medical treatment for acute systolic heart failure, without the use of lower extremity compression wraps.

If you are in group 2 (often called "Arm B"), you will receive standard medical treatment for acute systolic heart failure, with in addition you will receive lower extremity compression wraps.

The research study you are being asked to join involves collecting standard medical data routinely collected on all patients with a similar diagnosis in the hospital. These results can be made available to you at any time, by contacting the medical records department of Henry Ford Health System, or by activating and accessing MyChart. Your access to this data does not compromise your involvement in, or the results of, the research study.

5. WHAT ARE THE RISKS, DISCOMFORTS, OR INCONVENIENCES OF THE STUDY?

The researchers believe there are no reasonably foreseeable risks associated with this research study. There may be additional risks or discomforts that are not known at this time.

There may be additional risks or discomforts that are not known at this time.

Additional risks include a potential breach of confidentiality of your personal information. The measures taken to protect your personal information and any possible disclosure are described in the section below titled "*How will my personal information be protected?*"

A possible inconvenience may be the physical placement of the compression wraps on both legs. Blood

samples will be obtained from your veins. Possible side effects of obtaining blood samples are pain, bruising, bleeding, or infection at the blood draw site. Occasionally nausea, lightheadedness or fainting may occur. The collection of these samples will occur regardless of enrollment in this research study, as it is part of standard hospital management.

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study. If you are currently in another study, took part in one recently, or if you consider another study in the future, please inform the research staff right away.

6. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

The benefits of participating in this study may include decrease length of hospital stay, and improved lower leg swelling and edema.

7. WHAT OTHER OPTIONS ARE THERE AND WHAT ARE MY ALTERNATIVES?

Participation is voluntary. You do not have to participate in this study.

Your other choices may include receiving standard medical care for management of acute systolic heart failure, with or without the use of lower compression wraps as determined by your care provider team.

8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

Research records will not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. The researchers will label research records with a unique code and keep any master key that links your name and data and/or specimens in a separate location. The researchers will maintain all study records (including any codes) in a locked, secure location. Your research information will not be made a part of your regular medical record. If the researcher orders any tests, the order and results may become part of your regular medical record. All electronic files containing identifiable information will be password protected and only the members of the research staff will have access to the passwords. If researchers share your data and/or specimens with others, the information will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations. The researchers will maintain any data described in this paragraph in accordance with the security provisions of this paragraph until destroyed by the researchers by January 2021.

Your identifiable private information or identifiable biospecimen, even if stripped of identifiers, will not be used for future research studies or distributed to another researcher for future research studies without additional informed consent.

You should also know that the HFHS Institutional Review Board (IRB) and IRB Administration Office may inspect study records as part of its auditing program, but these reviews only focus on the researchers. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

9. WHAT IF I GET SICK OR I AM INJURED?

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study.

By signing this consent form, you do not give up any of your legal rights in the event of an injury.

10. WHO DO I CALL WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Cori Russel MD, or his/her staff member has explained this research study and has offered to answer any questions. If you have any additional questions about the study procedures, or to report an injury you may contact Raef Fadel DO by phone at 313-932-1347 or by email at rfadel2@hfhs.org. Medical treatment is available to you in case of an injury.

If you would like to discuss your rights as a research participant, discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research, you may contact the Henry Ford Health System IRB Administration Office by phone at (313) 874-4464 or by email at research_admin@hfhs.org. The IRB is a group of people who review the research to protect your rights.

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.

11. DO I HAVE TO PARTICIPATE IN THIS STUDY?

.You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. Inform the research staff/study doctor if you are thinking about stopping or decide to stop. There are no penalties or loss of benefits to which you are otherwise entitled if you decide that you do not want to participate.

If this happens, you may be asked to return for a visit for safety reasons. You will get the same medical care from HFHS whether or not you participate in this study. You will be told about any significant information that is discovered that could reasonably affect your willingness to continue

being in the study. You will be notified of all significant new findings during the course of the study that may affect your willingness to continue.

12. WHO ELSE CAN STOP MY PARTICIPATION?

The PI, sponsor, or your doctor can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons. There are no anticipated risks associated with enrollment in this study outside of standard medical care for management of acute systolic heart failure.

13. WILL IT COST ANYTHING TO PARTICIPATE?

We do not expect there to be any additional costs to you if you participate in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. You have the right to ask what it will cost you to take part in this study.

14. WILL I BE PAID TO PARTICIPATE?

There is no compensation available to you for your participation in this study.

Research using your data and biospecimens (including de-identified samples) can lead to new discoveries, such as the increased use of devices. However, your biospecimens will not be used for commercial profit.

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DOCUMENTATION OF CONSENT

By signing this form, I agree that I have read and understand this form and that I agree to participate in the research project described above. I have been given enough time and opportunity to ask about the details of the research study and to decide whether or not to participate. Its general purposes, the particulars of my involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time without giving any reason without my medical care or legal rights being affected. My signature also indicates that I have received a copy of this consent form.

The researchers in this study might want to ask you to participate in additional studies. In some cases, you might be a good candidate for a particular study because of your health history or genetic information.

I understand that this study involves wearing the compression stockings for the entirety of the hospital stay, and can only be removed for hygiene or comfort purposes with prompt reapplication. If you do not agree to comply with this requirement, you cannot participate in this study. I understand that it is my choice whether or not to take part in this study. Please initial below.

_____ I agree to comply with this requirement, and understand it is my choice alone.

_____ I refuse to comply with this requirement, which is my choice alone.

I understand that the investigator may use publicly available databases to determine whether I am living, for purposes related to my participation in this study only. Please initial below.

_____ I agree

_____ I refuse

I understand that this study involves video and/or audio recording and/or photography. If you do not agree to be recorded, you can still participate in this study. Please initial below.

_____ I agree to be video/audio recorded/photographed.

_____ I refuse to be video/audio recorded/photographed.

Signature of Subject	Date	Time
Printed Name of Subject		
Witness to Signature	Date	Time
Signature of Person Obtaining Consent	Date	Time
Printed Name of Person Obtaining Consent		

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INCOMPETENT/ILLITERATE ADULT SUBJECT

If applicable: I am unable to read but this consent document has been read and explained to me by _____ (name of reader). I volunteer to participate in this research.

_____	_____	_____
Signature of Subject/Representative	Date	Time

_____

Printed Name of Subject/Representative (and Relationship if Someone other than the Subject)

_____	_____	_____
Witness to Signature	Date	Time

_____	_____	_____
Signature of Person Obtaining Consent	Date	Time

_____

Print Name of Person Obtaining Consent