Pedal Pump Clinical Trial on Edema V1

Informed Consent

Principal Investigator: David McVay, DO

Hillcrest Medical Center

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HILLCREST MEDICAL CENTER

PATIENT INFORMATION AND INFORMED CONSENT FORM

Study Title: **Hillcrest Pedal Pump Clinical Trial on Edema V1**

Study Doctor: **David McVay, D.O.**

Introduction:
You are being asked to be in a research study. David McVay, D.O. (referred to in this informed consent form as "Study Doctor") is the doctor in charge of this study at this location. Before you decide if you want to be a part of this study, we want you to know the purpose of the study, how it may help you, any risks to you, what other choices you may have, and what is expected of you. This document also describes the privacy protection rules and who will have access to your medical and study records.

This form may contain words that you do not understand. Please ask the Study Doctor or nurse to explain any words or information that you do not clearly understand. You may discuss participation in this study with family and friends before making your decision. If you agree to take part in this study, you will be asked to sign this consent form. You should not sign this consent form if you have any questions that have not been answered.

Purpose:
You are being invited to participate in a research study being conducted to evaluate the performance of Pedal Pump, a patent pending motorized device developed by the Study Doctor. Pedal Pump is an investigational device. It has not received FDA approval.

If you agree to participate, you will lie down while the Pedal Pump will exert gentle, on-and-off pressure to your feet during a single treatment period lasting up to 15 minutes, with the goal treatment period being at least 10 minutes. The intended purpose of this device is to treat lower extremity (leg) swelling by mobilizing fluids in your body. Measurements of your ankles, thighs and calves will be taken before and after the treatment. You will also be asked to complete a brief survey. Your entire participation in this study should take about one hour.

Up to 60 patients may participate in this research study. You will be randomly assigned to the "treatment group" or the "non-treatment group," which will mean that you will either receive the treatment device or the non-treatment device. 40 patients will be in the "treatment group" and 20 patients in the "non-treatment group." Both groups can expect that their feet will be mobilized, their leg circumferences will be measured, and they will complete a brief survey.

Your doctor may be an investigator in this research study and, as an investigator, is interested both in your medical care and in the conduct of this research. Before entering this study, or at any time during the research, you may discuss your care with another doctor who is in no way associated with this research project. You are not under any obligation to participate in any research study offered by your doctor.

Benefits
This study may benefit you and other patients by decreasing lower extremity swelling. It may also increase blood flow to your heart and kidneys.

Risks
As with any medical treatment, there are risks associated with the use of Pedal Pump. These risks may include:

1. Minor risks: Mild to moderate irritation of skin, nerves, muscles, and blood vessels or blood pressure changes.
2. Serious risks: None have occurred to date.

All of these risks are unlikely, but possible. You will be monitored throughout the treatment and the pump can be stopped immediately upon request. You will not be tied down to the device and you can move your feet away from it at any time. Emergency care, although unexpected, will be available if needed. The device is experimental / investigational and has not been FDA approved, but the manual version has been used by physicians in the US for decades.

New Information
You will be informed of any significant new information that may affect your willingness to participate in the study. Alternative treatment options include: no treatment, increased exercise, lifestyle changes, and physical therapy.

Costs
There will be no cost to you or your insurance if you decide to participate in this study.

You will not receive a payment for participation in this study.

Compensation for Injury
If you are injured as a result of this study, you will receive medical care.

No funds have been set aside by Hillcrest Medical Center for any research-related injury, complication or unfavorable outcome resulting from this study. Treatment will be made available to you in the same way it is to all other Hillcrest Medical Center patients and the charges will be billed. You do not waive any legal rights by signing this consent form.

Confidentiality
The records of this study will be kept confidential and you will not be identifiable by name or description in any reports or publications. Records may be reviewed for research or monitoring purposes by Dr. David McVay and his assistants, the Hillcrest Medical Center Institutional Review Board, the FDA, the US Department of Health and Human Services and/or other government agencies.

In conducting this research study, the Study Doctor and members of his research team will access information from your medical records, including information about your medical history to determine whether you meet the study's criteria to participate. Additional information that will be collected from your medical records may include your name, gender, age, and data about your study treatment with Pedal Pump.

All reasonable measures to protect the confidentiality of your medical records and your identity will be taken. However, we cannot guarantee absolute confidentiality. All records related to your involvement in this research study will be stored in a secure location. The confidentiality of all study related records will be maintained in strict confidence as required by State and Federal laws. However, your health information may be disclosed if required by law.

You will not be identifiable by name or description in any reports, presentations, or publications that may result from this study. In order to ensure the accuracy of the research results, and to make sure the research is conducted properly, agents of the Hillcrest Medical Center Institutional Review Board, and authorized representatives of Federal or State government agencies may review and/or copy your medical records relevant to your participation in this study. Once your health information is disclosed for research, federal privacy laws may no longer protect the information.

- By signing this consent form to participate in this study, you are authorizing the study doctor and the research team to access and share your private health information, as described in this consent form.
- You do not have to give your permission for the research staff to use or give out your health information. However, if you do not give your permission, you may not participate in this study.
- Your have the right to revoke your authorization for the access and sharing of your private health information. If you revoke your authorization, you will be withdrawn as a participant in the research study. All information gathered before that date will continue to be used. To revoke your authorization, you must do so by writing to: David McVay, D.O. at 5148 E. 30th Place, Tulsa, OK 74114.
- Your authorization for the sharing of your private health information for this study does not end.
- The study doctor will maintain your study records for 6 years after publication or submission of the information. Any research information in your regular medical record will become a permanent part of that record.

Subject Assurances

For questions about this study or to report an injury, call David McVay, D.O. or his designees at 918-376-0107.

For questions about your rights as a research subject you may contact the Hillcrest Medical Center Institutional Review Board at 918-579-1072, or send an email to Dorene.Taqi@Hillcrest.com.

You have not given up any of your legal rights or released any individual or institution from liability for negligence. You may withdraw from this study at any time, without penalty or loss of benefits to which you are otherwise entitled. Your treatment by and relations with the physicians and organizations involved in this study will not be affected now or in the future, if you decide not to participate, or if you start the study and decide later to withdraw.

Your participation in this study is voluntary. You can choose not to take part in the study and you will not lose any benefits to which you are entitled. You will receive a signed copy of this consent form.

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.

Consent Statement

I have read this consent form or it has been read to me and clearly explained in a language I understand. My questions have been answered to my satisfaction. I freely consent to participate in this study. I agree to the release of records for review as described under the above conditions. I understand that this consent may be cancelled at any time. I have been told of the potential risks and agree to participate in this research. I will receive a copy of the Hillcrest Medical Center "Research Subject's Bill of Rights" and a copy of this completed, signed consent form.

_____

Subject's Name (printed)

_____

Signature of Patient Date

_____

Email of Patient (if you would like a copy of the research paper when published)

_____

Printed Name of Person Obtaining Consent

_____

Signature of Person Obtaining Consent Date

Hillcrest Medical Center, Tulsa, and Oklahoma Heart Institute

Research Subject's

Bill of Rights

The rights below are the rights of every person who is asked to be in a research study. As a volunteer research subject, I have the following rights,

1. To be told what the study is trying to find out and what it will cost me to participate.
2. To be told of the risks, side effects, or discomforts that may happen to me during my treatment,
3. To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,
4. To be told of the other choices I have and how they may be better or worse than being in the study,
5. To be told of the other choices I have and how they may be better or worse than being in the study,
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,
7. To be told what sort of medical treatment is available if any complications arise,
8. To refuse to participate at all or to change my mind about participation after the study is started and to be sure this decision will not affect my right to receive the care I would receive if I were not in the study,
9. To receive a copy of the signed and dated consent form,
10. To be free of pressure when considering whether I wish to agree to be in the study,
11. To know if the research investigator/doctor is receiving financial remuneration for my participation in this study.

If I have other questions, I should ask the research or the research assistant. In addition, I may contact the Institutional Review Board at Hillcrest Medical Center, which is concerned with protection of volunteers in research projects. I may reach the Board by calling (918) 579-1072 from 8:00 am to 5:00 pm, Monday to Friday or by writing to the Institutional Review Board, Hillcrest Medical Center, 1120 South Utica Avenue, Room 2709, Tulsa, OK 74104.

Authorization to Use and Disclose Health Information for Research Purposes

What is the purpose of disclosing your information? Medical research involves the sharing of information that you may consider to be private. In order to disclose your private health information, we need your permission. Your information will be used or disclosed under this authorization only for the purposes identified in your signed Informed Consent Form for the following protocol:

Study Title: Hillcrest Pedal Pump Clinical Trial on Edema

Study Doctor and Study Sponsor: David McVay, D.O.

What Information is Necessary? Information needed for this study will mostly be in your medical and research records. This includes, but is not limited to things like the following:

- Your Medical History and Diagnosis.
- Results from procedures described in your Informed Consent Form.
- Results from research related care while in the study.
- Notes from Doctors, Nurses or other people involved in your research or care.
- Forms you fill out yourself.
- Forms other people may fill out about your condition or symptoms.
- Collected specimens and information from tests run on them.
- Other information about your health condition or symptoms including physical and mental health.

Sometimes, researchers need to know more than what is in that research record. They may also need to double-check some research results. Because of this, it may be necessary to disclose parts of your medical record as well.

Some personal information may also be disclosed. This information may include your name, date of birth, gender and race. Information about your health and sex life (such as contraception practices) may also be necessary.

Who will be disclosing this information? Our research and medical records staff will be in charge of releasing this information.

Who will receive this information? Several agencies are working as a team in this research. They will need to share portions or all of your information with each other. These people may include but are not limited to the following:

- Study Doctor and the research staff.
- Study Sponsor (mentioned above).
- The United States Food and Drug Administration (FDA) or other regulating government body.
- The FDA's equivalent in other countries, which may have different privacy laws.
- Hillcrest Medical Center Institutional Review Board (IRB) members. This is the ethics board that reviews and gives ongoing approval to conduct the study.
- Data and Safety Monitoring Boards.

Will the information be further disclosed? All health care providers are required by law to help protect the privacy of your information. As you see though, many people are involved in this research. It is possible that the federal privacy laws may not apply to some of the parties that receive your information, such as the Sponsor. If that happens, you may have to rely on their privacy policies instead of the law. The results of the study may be published. If so, there will be nothing that can identify you in that publication.

Will I have access to my records? You may not be able to see or copy portions of your records during this study. When the study is completed, you will have the usual access to your records again. You will, however, have a signed copy of this form and your Informed Consent Form. For more questions on your access, please see our Notice of Privacy Practices.

Can I refuse to sign this form? You have a right to refuse to sign this form. You will, however, not be able to enroll in the research study, and research-related treatment may not be available to you.

How long is this authorization good for? The above people may need to review your information again many years in the future. This could be for any follow-up or statistical purposes related to this study. Your information may be stored in a database for this purpose as well. Because of this future need, this authorization does not expire.

Can I change my mind after I sign? You may change your mind at any time. To revoke this authorization, please write to our address in our Notice of Privacy Practices. This study, however, is dependent on your information. If you revoke this permission, you will not be allowed to continue in the study. Also, information collected before you revoked your permission can still be used to protect the integrity of the study.

I have read this form. All of my questions about this form have been answered. By signing below, I authorize the described uses and disclosures of my health information.

Research Participant

_____
Signature of Participant

_____
Date

_____
Printed Name of Participant

OR

Personal Representative

_____
Signature of Personal Representative

_____
Date

_____
Printed Name of Representative

_____
Description of Legal Authority to Act