RESEARCH PARTICIPANT CONSENT FORM

A new heat therapy device for home-based leg heating in patients with lower-extremity peripheral artery disease: a pilot study

Small Business Innovation Research Grant (SBIR), National Institute of Health, National Heart, Lung, and Blood Institute (NHLBI)

Key Information

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent and Authorization form will give you information about this study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form, and ask any questions you have, before agreeing to be in this study.

What is the purpose of this study?

The purpose of this study is to investigate whether daily treatment with heat therapy for 12 weeks improves your walking ability and the strength of your leg muscles. Heat therapy will be applied to your legs, thigh and buttocks using a newly developed leg heat therapy system. This new system is comprised of leg-length water circulating pads surrounded by a separate air-filled compression outer garment that compresses the pads against the skin. The leg garment is closed with a zipper. The air chambers automatically adjust the amount of air inflation enabling use of the garment independent of leg size.

You will be given a pair of water-circulating trousers and a portable control unit and will be asked to apply the therapy every day for 90 min for 12 weeks in a row. Before the treatment and at the end of the of treatment (12 weeks ± 7 days) you will have a series of exams, including a walk test and leg strength testing.

We are asking you if you want to be in this study because your medical records indicate that you have been diagnosed with peripheral artery disease or because you completed prior studies and expressed interest in future research.

The study is being conducted by Dr. Bruno Roseguini, Department of Health and Kinesiology Purdue University. It is funded by a Small Business Innovation Research Grant (SBIR) from the National Heart, Lung, and Blood Institute (NHLBI).

You will be one of 8 participants taking part in this study.

What will I do if I choose to be in this study?

If you agree to be in the study, you will initially be asked to come to the laboratory on two different occasions to complete baseline testing. You will need to fast (do not eat anything – do not drink beverages with calories) overnight prior to the study but will be asked to take your medication normally. You will also be required to abstain from alcohol and exercise for 24 hours and from smokingfor at least 4 hours before this visit.

PHASE I (BASELINE TESTING)

Visit 1 - (Duration 3 hours) LAMBERT ROOM 8

1. The investigator will ask you to fill out a medical history form. This form contains questions about your current health status, treatments that you received and the medications you are currently taking. They will also ask about your age, race, ethnicity, and gender.

2. You will be asked to fill out an 11-question test, called a Mini-Mental Status Examination (MMSE) to assess your mental health.

3. Your ability to detect increases in temperature (thermal sensation) in multiple locations on your thighs and calves will be tested. To do this, an electric heating pad and another pad maintained at room temperature will be used. A portion of the room temperature pad and a portion of the heated pad will be placed in each location and you will be asked whether you feel heat or not.

4. You will be escorted to an examination room and will be asked to lie down on a bed for the measurement of blood pressure in your arms and ankles. Cuffs will be wrapped around your arms and ankles and you will be asked to rest quietly for 10 minutes. Next, ultrasound gel will be applied to the areas where the measurements will be made on your arms and ankles. A device will be used to measure the blood pressure in the artery of your arms and ankles. This is called an ABI measurement. This test compares the blood pressure measured at your ankle with the blood pressure measured at your arm. You will also be asked to do toe stands for 30 seconds before the exam is repeated. You will stand with your feet shoulder-width apart near a counter or chair. You will be asked to push up as far as you can onto the balls of your feet and then slowly lower your heels back to the floor. You will repeat toe stands for 30 seconds and then lay back on the examination table. The blood pressure measurements in your ankle will be repeated.

5. Your blood pressure will be measured three times in a row in your non-dominant arm after 3 minutes of rest.

6. Your body weight, height, waist circumference, thigh circumference and calf circumference will be

measured and recorded.

7. After the blood pressure measurements are completed, you will be asked to complete the 6-min walk test which consists of walking back and forth along a 100-ft corridor around plastic cones for 6 minutes. The goal of this test is to walk as far as possible. You are permitted to slow down, to stop, and to rest as necessary. You may lean against the wall while resting and resume walking as soon as you are able. If you experience chest pain, dizziness, shortness of breath or any other abnormal symptom that you do not typically experience when you walk, please report it to the investigators.

8. You will undergo the assessment of the strength of your calf muscles on a dynamometer. A dynamometer is an evaluation equipment that's used to measure muscle force. Your foot will be strapped to the exercise equipment, which consists of a foot pedal. You will be asked to press down the pedal just like you would do on the gas pedal of your car. This test is expected to last approximately 30 min.

9. Finally, you will be asked to complete the repeated chair rises test, which measures the time required to complete 5 repeated chair stands. You will be asked to sit on a standard padded chair without armrests and cross your arms against your chest. Starting from the seated position, you will be asked to stand up (legs straight) and sit down (full weight on the chair) 5 times in a row. You will be asked to complete two tests with a 5-min rest interval between trials.

Visit 2 - (Duration 3.5 hours) LAMBERT ROOM 8

At least three days after visit 1, you will be asked to return for a second visit (visit 2). You will be asked to fast (not eat or drink beverages with calories) overnight prior to the visit. You will also be required to abstain from alcohol and exercise for 24 hours and from smoking for at least 4 hours before this visit. You will undergo the following procedures:

1. You will be asked to fill out a questionary about your quality of life and problems you have with walking, called the Walking Impairment Questionnaire.

2. Your blood pressure will be measured three times in a row in your non-dominant arm after 3 minutes of rest.

3. After the blood pressure measurements are completed, you will be asked to complete the 6-min walk test like in Visit 1.

4. You will be asked to complete the calf strength test like in Visit 1.

5. Next, you will be asked to complete the repeated chair rises test like in Visit 1.

6. After this test is complete, you will be escorted back to the examination room. You will be given a nutrition shake and will be allowed to rest in the seated position for 15 min.

7. You will then be familiarized with the heat treatment and will receive detailed instructions about how to operate the equipment and apply the therapy at home.

8. First, skin temperature sensors that have the size of a dime will be taped to the skin on your thighs and legs to measure temperature during this familiarization with the treatment. Also, a conventional blood pressure cuff will be placed around your arm for blood pressure measurements via an automated device.

9. You will be asked to dress water-circulating 'pants' that will be used to apply heat to your lower body. This system is comprised of leg-length water circulating pads surrounded by a separate air-filled compression outer garment that compresses the pads against the skin.

10. The garment will be connected to a small pump that will circulate warm water through the pants for 90 min.

11. Blood pressure and skin temperature will be measured throughout the entire protocol.

12. After the treatment is completed, the coordinator will teach you how to inspect the skin in your legs, thighs and buttocks to look for adverse reactions to the treatment, how to wash and care for the water-circulating trousers and how to fill the pump with water after each treatment session.

PHASE II (Treatment)

- After initial testing is complete, you receive a pair of water-circulating trousers that perform heat therapy and a portable heat pump. You will be instructed to apply the therapy daily for 90 min for 12 weeks. You will be able to choose what time each day that you will apply the therapy. You should be sitting with the legs extended or lying in bed while applying the therapy. It is very important that you remain in position with your legs extended and keep the pants on for the full 90 minutes. You will not be able to move around for 90 minutes. The water heater is equipped with an auto shut-off device that will automatically turn off after 90 min. If you feel a burning feeling or experience any other adverse effects, please stop the treatment immediately and call the study coordinator.

- You will be provided a blood pressure monitor and will be instructed to take 2 readings at least 1 min apart in the sitting position prior to and immediately after the end of each heat treatment.

- You will also receive a logbook and will be asked to write down the exact times you underwent the therapy daily and the blood pressure before and after the treatment. If for some reason your 90-min session is interrupted, please make note of that in your logbook. Try to resume the therapy as soon as possible so that the full 90 min of treatment are completed.

- You will be asked to clean the water- circulating trousers at least once every week.

- The study coordinator will call you each week to ask you the days and times you applied the therapy and your blood pressure before and after each treatment. The coordinator will also ask you about your health status. If your health changes during the duration of your participation in the experiment or if any changes are made to your medications, please inform the study coordinator.

PHASE III (END OF TREATMENT EXPERIMENTAL VISIT)

After 12 weeks of daily treatment, you will be asked to return to the laboratory for the end-treatment assessment.

Visit 3 - (Duration 1.5 hours) LAMBERT ROOM 8

Visit 3 will be conducted 12 weeks ± 7 days after visit 2. You will undergo the following procedures:

1. You will be asked to stop the heat therapy treatment for at least 48 hours prior to Visit 4.

2. You will fast overnight (do not eat anything – do not drink beverages with calories) prior to the visit - you may take morning medications. You will also be required to abstain from alcohol and exercise for 24 hours and from smoking for at least 4 hours before this visit.

3. You will be asked to grade the device usability using the System Usability Scale (SUS). Scores range from 0 to 100; > 70 represents acceptable usability.

4. You will undergo the same procedures as Visit 2, except for the leg heat therapy system testing.

How long will I be in the study?

You will be in the study for approximately 4 months.

What are the possible risks or discomforts?

The procedures involved in this research protocol involve some risks and side effects as described below. You should discuss these with the investigators before agreeing to participate in this study. Risks and side effects related to the procedures we are studying include:

Leg heat treatment: During the treatment with heat therapy, heated water will be pumped through the water-circulating pants to heat your lower-body. You should apply the therapy while sitting with the legs extend or while lying in a bed. You should only apply the therapy for 90 min daily. The skin in contact with the garment pants will get red after the therapy and you may experience discomfort during the treatment due to a feeling of warmth/heat. If you feel a burning feeling, please stop the treatment, and call the study coordinator. Adverse reactions to heat treatment are rare but it is possible that the therapy might cause skin blistering, burns, and pain and swelling of the area. You will be trained to examine the skin after each treatment session for potential signs of injury or adverse reactions to the treatment. Stop the treatment immediately if any adverse signs are observed.

6-min walk test: Adverse responses to this exercise test are rare, but you may slip, stumble and fall. There is a minor chance that you may experience: chest pain, difficulty breathing, dizziness, leg cramps, staggering, sweating, and shortness of breath. If you feel any of these symptoms, please stop walking and report it immediately to the investigators.

Calf strength test: This protocol might cause a feeling of tiredness, pain and local muscle discomfort. These feelings are temporary and should disappear after a short recovery period.

Repeated chair rises test: This protocol might cause a feeling of tiredness, pain, local muscle discomfort, shortness of breath, leg cramps and dizziness. These feelings are temporary and should disappear after a short recovery period.

Blood pressure measurement: A blood pressure cuff will be wrapped around your arm. You may feel discomfort when the blood pressure cuff is inflated.

Quality of life questionnaires: A risk of completing the quality-of-life survey is being uncomfortable answering the questions. While completing the survey, you can tell the researcher that you feel uncomfortable or do not want to answer a particular question.

There is a risk of loss of confidentiality. Breach of confidentiality is always a risk with data, but we will take precautions to minimize this risk as described in the confidentiality section.

There also may be other side effects that we cannot predict.

Are there any potential benefits?

If you agree to take part in this study, you may benefit from the heat therapy treatments and experience a reduction in pain in your legs that occur while walking; however, there is no guarantee that you will experience these benefits. We are doing this research study to find out if this treatmenthelps or not.

What alternatives are available?

There may be other options for treatment of your peripheral vascular disease. You may choose not to participate in the study.

Will I receive payment or other incentive?

You will receive a total of $500 for taking part in this study. You will be compensated $200 after the completion of the baseline testing, and $300 after the completion of the study.

Are there costs to me for participation?

There is no cost to you for taking part in this study.

This section provides more information about the study

What happens if I become injured or ill because I took part in this study?

If you feel you have been injured due to participation in this study, please contact Bruno Roseguini at 765-496-2612. Purdue University will not provide medical treatment or financial compensation if you are injured or become ill as a result of participating in this research project. This does not waive any of your legal rights nor release any claim you might have based on negligence.

Will information about me and my participation be kept confidential?

The project's research records may be reviewed by the study National Heart Lung and Blood Institute, Food and Drug Administration (if FDA regulated), US DHHS Office for Human Research Protections, and by departments at Purdue University responsible for regulatory and research oversight.

This study is funded by the National Heart Lung and Blood Institute.

The project's research records may be reviewed by departments at Purdue University responsible for regulatory and research oversight. Information produced by this study will be stored in the investigator's file and identified by a code number only. The code key connecting your name to specific information about you will be kept in a separate, secure location. Information contained in your records may not be given to anyone unaffiliated with the study in a form that could identify you without your written consent, except as required by law.

The results of this study may be published in a medical book or journal or used for teaching purposes. However, your name or other identifying information will not be used in any publication or teaching materials without your specific permission. Your name and social security number will be given to the business office for facilitating payment, but will not be used for any other purposes.

Clinicaltrials.gov

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

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The

researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. For additional information about CoCs see http://grants.nih.gov/grants/policy/coc/faqs.htm."

What are my rights if I take part in this study?

You do not have to participate in this research project. If you agree to participate, you may withdraw your participation at any time without penalty.

Who can I contact if I have questions about the study?

If you have questions, comments or concerns about this research project, you can talk to one of the researchers. Please contact Bruno Roseguini at 765-496-2612.

To report anonymously via Purdue's Hotline see www.purdue.edu/hotline

If you have questions about your rights while taking part in the study or have concerns about the treatment of research participants, please call the Human Research Protection Program at (765) 494-5942, email (irb@purdue.edu) or write to:

Human Research Protection Program - Purdue University

Ernest C. Young Hall, Room 1032

155 S. Grant St.

West Lafayette, IN 47907-2114

DOCUMENTATION OF INFORMED CONSENT

I have had the opportunity to read this consent form and have the research study explained. I have had the opportunity to ask questions about the research study, and my questions have been answered. I am prepared to participate in the research study described above. I will be offered a copy of this consent form after I sign it.

_____ _____

Participant's Signature Date

_____

Participant's Name

_____ _____

Researcher's Signature Date

this document to keep for my records.