Consent Form

University of Oklahoma Health Sciences Center (OUHSC)

Noninvasive Neuromodulation to Reverse Diastolic Dysfunction (NERDD)

Principal Investigator: Stavros Stavrakis, MD, PhD

This is a clinical trial (a type of research study). Clinical trials include only patients who choose to take part in them. Please take your time to make your decision. Discuss this with your family and friends.

Why Have I Been Asked To Participate In This Study?
You are being asked to take part in this study because you have been diagnosed as having diastolic dysfunction (stiffness of the heart muscle).

Why Is This Study Being Done?
The purpose of this study is to find out whether low-level, electrical stimulation of the ear, using a transcutaneous electrical nerve stimulation (TENS) device, can improve heart function. This is assessed by using an echocardiogram (ultrasound of the heart) and an electrocardiogram (EKG).

We will explain how a TENS unit works below:

The TENS unit is a small, portable, battery-powered device. It sends low-level, electrical pulses to the nerves under the skin of your ear through an ear clip attached to the ear.

What is the Status of the Device Involved in This Study?
A transcutaneous electrical nerve stimulation (TENS) device is used for the purpose of ear stimulation in this study. The device is not approved for this use by the US Food and Drug Administration, and is being used in this study as an investigational device. This device has been studied in another heart condition called atrial fibrillation and was found to be safe and well tolerated at the pulse levels used in this study.

How Many People Will Take Part In The Study?
About 26 people will take part in this study all at this location.

What Is Involved In The Study?
You will receive two separate, one hour sessions, at least one day apart, of active and inactive TENS stimulation. The sequence of the sessions will be randomized (active/inactive or inactive/active). Randomization means that you are put in a group by chance, like the flip of a coin. A computer program at the study site will make this random assignment. You will not know what group you are assigned to. The stimulation will be accomplished by using a TENS device with a special ear clip electrode which can attach easily to the ear. During each visit, you will have an echocardiogram and a series of four, five-minute EKG recordings that will be obtained every 15 minutes of

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stimulation. You will be asked to lay on your back and your left side for approximately one hour to perform the echocardiogram and the series of EKG recordings.

How Long Will I Be In The Study?
Participation will last for two one-hour sessions, at least one day apart.

What Are The Risks of The Study?
Use of the TENS device for electrical ear stimulation therapy may involve risks that are currently unforeseeable.

TENS therapy is very safe and well tolerated when used correctly. You could experience some numbness, tingling or mild skin irritation at the site of application on your ear. More significant side effects like heart arrhythmias are extremely rare.

Are There Benefits to Taking Part in The Study?
If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope that the information learned from this study will benefit other patients with this disease in the future.

What Other Options Are There?
You may choose not to participate in the study.

What About Confidentiality?
Efforts will be made to keep your personal information confidential. You will not be identifiable by name or description in any reports or publications about this study. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. You will be asked to sign a separate authorization form for use or sharing of your protected health information.

There are organizations outside the OUHSC that may inspect and/or copy your research records for quality assurance and data analysis. These organizations include the US Food & Drug Administration and other regulatory agencies. The OUHSC Human Research Participant Program office, the OUHSC Institutional Review Board, and the OUHSC Office of Compliance may also inspect and/or copy your research records for these purposes.

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

What Are the Costs?
There no costs associated with participation in the study.

What if I am Injured or Become Ill While Participating in this Study?
In the case of injury or illness resulting from this study, emergency medical treatment is available. No funds have been set aside by The University of Oklahoma Health Sciences Center to compensate you in the event of injury.

What Are My Rights As a Participant?
Taking part in this study is voluntary. You may choose not to participate. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. If you agree to participate and then decide against it, you can withdraw for any reason and leave the study at any time. Please be sure to discuss leaving the study with the study doctor or your regular doctor. You may discontinue your participation at any time without penalty or loss of benefits, to which you are otherwise entitled.

You have the right to access the medical information that has been collected about you as a part of this research study. However, you may not have access to this medical information until the entire research study has completely finished and you consent to this temporary restriction.

Whom Do I Call If I have Questions or Problems?
If you have questions, concerns, or complaints about the study or have a research-related injury, Dr. Stavros Stavrakis can be reached 24 hours a day, seven days a week at the following number: 405-271-9696.

If you cannot reach the Investigator or wish to speak to someone other than the investigator, contact the OUHSC Director, Office of Human Research Participant Protection at 405-271-2045.

For questions about your rights as a research participant, contact the OUHSC Director, Office of Human Research Participant Protection at 405-271-2045.

Signature:
By signing this form, you are agreeing to participate in this research study under the conditions described. You have not given up any of your legal rights or released any individual or entity from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

I agree to participate in this study:

_____	_____	_____
PARTICIPANT SIGNATURE (age ≥18)	Printed Name	Date
_____	_____	_____
SIGNATURE OF PERSON OBTAINING CONSENT	Printed Name	Date

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