University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 1-28-2023
IRB Study # 21-3127
Title of Study: Internal Jugular Vein Compression Collar for Novel Symptomatic Treatment of Venous Pulsatile Tinnitus
Clinical Trial Number: NCT05441540
Principal Investigator: Benjamin Succop
Principal Investigator Department: School of Medicine Office of Graduate Education
Principal Investigator Phone number: 8284439726
Principal Investigator Email Address: benjamin_succop@med.unc.edu
Faculty Advisor: Brian Sindelar
Faculty Advisor Contact Information: (919) 966-1374

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CONCISE SUMMARY
Venous pulsatile tinnitus is a specific subtype of tinnitus with limited treatment options. It is defined as a "whooshing" sound that pulsates in rhythm with the patient's heartbeat and generally manifests unilaterally (in a single ear). It can be highly detrimental to hearing and quality of life. This condition is diagnosed and distinguished from other types of tinnitus by a physician lightly compressing the internal jugular vein ipsilateral to the side of symptoms and achieving temporary symptom relief for the duration of compression that ends when the compression stops.

It is the goal of this study to test an internal jugular vein compression collar as a symptomatic treatment for patients with the condition of venous pulsatile tinnitus. By replicating, applying, and extending a sustained mild compressive technique already used by physicians on exam, it is hypothesized that this collar will achieve significant, perhaps even complete reduction in patient symptoms. If successful, the collar can offer patients who suffer from untreatable venous pulsatile tinnitus an opportunity for sustainable symptomatic relief.

The collar has no known risks in its existing FDA approved application in individuals 13 or older participating in contact sports; any adverse effects are to be reported immediately to the investigators of the project using the contact information above. The greatest likelihood of any side effect is discomfort.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There

also may be risks to being in research studies.
Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to assess the effectiveness of an FDA approved internal jugular vein compressoin collar in releiving the symptoms of venous pulsatile tinnitus.

You are being asked to be in the study because you are a patient at UNC Meadowmont ENT Clinic who has a diagnosis of venous pulsatile tinntius.

This collar has been approved by the FDA with no significant risks for use in preventing cerebral injury in contact sports, this study seeks to evaluate its effectiveness in a new application of treating venous pulsatile tinnitus.

If you participate, you may benefit by experiencing symptom relief while wearing the collar in this study.

Are there any reasons you should not be in this study?
You should not be in this study if you do not have a diagnosis of venous pulsatile tinnitus. Additionally, you should not be in this study if your age is <18, you are unable to provide written consent, have a history of neurological deficits, previous cerebral infarction (blockage or narrowing in the arteries supplying blood and oxygen to the brain) or severe head trauma, have medical contraindications to restriction of blood outflow via the internal jugular veins, glaucoma (narrow angle or normal tension – increased pressure in the eyes), hydrocephalus (increased fluid on the brain), recent penetrating brain trauma (within 6 months), known carotid hypersensitivity, known increased intracranial pressure, idiopathic intracranial hypertension, known intracranial vascular malformation (aneurysm, arteriovenous malformation, cavernoma, etc.) central vein thrombosis, any known airway obstruction, or cannot tolerating initial fitting of the collar. You should not be in this study if you know that you are pregnant or trying to become pregnant. You should not be in this study if you do not speak and read English.

How many people will take part in this study?
Approximately 20 participants at UNC Meadowmont ENT clinic will take part in this study.

How long will your part in this study last?
Your participation will begin with an initial clinic visit where the collar is fitted and assessed. If you have symptomatic relief, you will be given the option to take the collar home and asked to chart once daily your average daily tinnitus intensity with and without the collar for 2-4 weeks. You will then return to clinic to complete exit surveys, offer your feedback, return the device

What will happen if you take part in the study?
First, you will be asked to rate your tinnitus on a tinnitus intensity scale at clinic. You will then

be fitted with the internal jugular vein compression collar and asked to complete the intensity scale after 10 minutes of wearing. The scale will be administered by tablet through a secured link into the study's REDCAP database. You will have the option of having your pulsatile tinnitus recorded with a digital amplified stethoscope before and after collar fitting, please mark at the end of this form if you are willing to undergo this additional step.

Then, if the collar provides relief, you will take it home for personal use for 2-4 weeks before returning to clinic. During that time, you will be able to use the collar for symptomatic relief while you are awake. It is important that you do not wear the collar while sleeping to minimize risk of discomfort or improper use. You will be asked to record your average tinnitus intensity once daily with and without the collar.

Lastly, you will return to clinic after the 2-4 week testing period to return the collar, complete exit surveys, and debrief your experience.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may be symptomatic relief of your venous pulsatile tinnitus while wearing the collar.

What are the possible risks or discomforts involved from being in this study?

The collar is FDA approved for wearing contact sports, and there are no adverse events associated.

The FDA warns against misuse of the collar, which could lead to neck pain and/or rsyncope (dizziness). In order to prevent this from occurring, a healthcare provider member of the team will educate you on the color use, fit you with the collar, show you how to adjust the collar, and send you home with collar instructions. Though the risk of such an adverse event is unlikely, it is vital that you adhere to all instructions regarding collar use for maximization of your safety.

Additionally, there is a possibility that you will feel discomfort when wearing it. Care will be made to ensure the fitting is optimize your needs. There is also possibility of mild discomfort if collar used incorrectly; this will be averted by the team fitting the collar correctly to your neck circumference at the initial visit and by you not using the collar while sleeping.

There could be psychological distress from answering questions around anxiety or depression via the quality of life surveys administered once at the beginning of the study and once at the end. The Substance Abuse and Mental Health Services Administration (SAMHSA) National Helpline is 1 800-662-HELP (4357) offers resources. Should you experience a mental health emergency please dial your emergency department and contact your physician. Additionally, you may contact the faculty advisor for this project and they will advise you towards one of these resources. Any mental health emergency detected by the team either through participation or the surveys will be referred to a care provider for support.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

Will I receive any other clinical results?
Clinically relevant results of this research will be communicated with you by email after data analysis

How will information about you be protected?
Your information, participation, and survey responses will be uploaded to a secure healthcare research database called REDCAP. REDCAP is a national standard for HIPAA compliant, safe storage and analysis of research data including PHI. Only HIPAA trained study personnel will have access to your data. After analysis, your identifying information will be deleted and aggregate results from the study will be shared for scientific presentation.

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the

right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected will be destroyed and no additional data will be collected. You will be asked to return the collar and any related equipment that were given to you for the purpose of the study.

Will you receive anything for being in this study?
You will not receive anything for taking part in this study.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

In addition to your participation, would you be willing to have your pulsatile tinnitus recorded with a digital amplified stethoscope before and after collar fitting? Your answer does not affect your participation in the study.

_____ Yes _____ No

_____
Signature of Research Participant

_____
Date

_____
Printed Name of Research Participant

_____
Signature of Research Team Member Obtaining Consent

_____
Date

_____
Printed Name of Research Team Member Obtaining Consent

_____
Signature of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form)

_____
Date

_____
Printed Name of Witness