Internal jugular vein compression collar for novel symptomatic treatment of venous pulsatile tinnitus

Promoteur(s) : University of North Carolina, Chapel Hill

Recrutement : fermé

CENTRES PARTICIPANTS

Dernière modification : 2023-08-22

DESCRIPTION DE L’ÉTUDE

This study seeks to pilot an evaluation of whether an external jugular vein compression collar approved by the FDA for contact sports can provide symptomatic relief of venous pulsatile tinnitus. Furthermore, the study will evaluate quality of life impacts of the device and adherence by users.

Background: Tinnitus is a medical condition with a wide variety of causes that is characterized by the perception of sound, often described as ringing or buzzing, without an external stimulus. Venous pulsatile tinnitus is a specific subtype of tinnitus with limited treatment options: some cases can be treated with surgical correction of an underlying vascular defect, others are entirely idiopathic. The clinical diagnostic hallmark of venous pulsatile tinnitus is relief of symptoms with light compression of the ipsilateral external jugular vein by the physician. Internal jugular vein compression collars, FDA approved devices currently used to prevent brain injuries in contact sports, function by this exact same method. Therefore, it is believed that these collars can treat pulsatile tinnitus.

Study Design:

This is a non-blinded, interventional, prospective single cohort pilot study that will recruit 20 patients diagnosed with pulsatile tinnitus at the UNC Meadowmont ENT clinic (see methods for inclusion/exclusion criteria). Volunteers will compare tinnitus intensity before and after administration of the collar, take the collar home and evaluate its symptomatic efficacy over a 2-4-week period, and return to clinic to complete data on quality of life and longitudinal impacts. This data will be analyzed for significance.

Expected Outcomes:

It is expected that collar administration will offer immediate symptomatic relief, illustrated as significant improvement on the tinnitus intensity scale during their initial clinic visit. Symptomatic improvement will be sustained while wearing the collar, measured by sustained improvement in the tinnitus handicap inventory over the course of the study. Lastly, the collar will improve quality of life as measured by patient reported outcome scales administered pre and post participation.

RECRUTEMENT

Profil des participants

• All

Condition médicale (spécialité visée)

Domaine de recherche
• Pulsatile Tinnitus

Critères de sélection

Inclusion Criteria

Male or female age 18 years and older
Diagnosis of venous pulsatile tinnitus
Patient at UNC ENT Meadowmont Clinic

Exclusion Criteria
Increased presence of acid in the body or excessive blood alkalinity
Open head injury (including in or around the eye) within the past six months
Pseudotumor cerebri (false brain tumor)
Presence of brain or spinal shunt
Known seizure disorder
Known airway obstruction
Increased likelihood of blood clotting (coagulation)
Skin injury, rash, or other abnormality on or around the neck
age <18 unable to provide written consent,
history of neurological deficits,
previous cerebral infarction (blockage or narrowing in the arteries supplying blood and oxygen to the brain)
severe head trauma
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 (e.g. aneurysm, arteriovenous malformation, cavernoma)
central vein thrombosis
not tolerating initial fitting of collar.
Known pregnancy (this is not a direct contraindication but is being made out of an abundance of caution)
Inability to speak or comprehend English

Cohortes
Donnée non disponible

LOCALISATION ET CONTACTS

Centre principal

UNC MEADOWMONT ENT CLINIC
CHAPEL HILL, NORTH CAROLINA
Recrutement local: FERMÉ

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