ClinicalTrials.gov Identifier: NCT04120129

Transcranial Magnetic Stimulation (TMS) for Trigeminal Neuralgia (TGN)

Information provided by Mark Witcher, Carilion Clinic (Responsible Party)

Last Updated: November 10, 2020

Study record dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

FIRST SUBMITTED	FIRST SUBMITTED THAT MET QC CRITERIA	FIRST POSTED

August 23, 2019	October 8, 2019	October 9, 2019

Study Record Updates

LAST UPDATE SUBMITTED THAT MET QC CRITERIA	LAST UPDATE POSTED	LAST VERIFIED
November 10, 2020	November 13, 2020	November 2020

Study Tab

Study Overview

Brief Summary:

The primary objective is to establish the feasibility of using TMS for COFP pain management in the interim period before surgery. This will be investigated by comparing the non-intervention group's self-reported pain to those who recieved TMS at several timepoints.

Detailed Description:

Participants will be randomized to either receive transcranial magnetic stimulation (TMS), Sham-TMS (a non-therapeutic TMS coil which sounds and feels similar to normal TMS), or standard treatment during the weeks of wait time before surgery for chronic orofacial pain (COFP). TMS is a noninvasive, painless magnetic device which, when applied to the head for a few minutes, has been shown to reduce pain in people with COFP. The sham TMS is a sub-therapeutic level of magnetcic stimulation which makes the same sound as normal TMS and causes a similar tingling of the skin.

Both those who receive this new pain intervention and those who do not will be asked to fill out a short online survey about their pain at several points during the study. The survey takes about 10 minutes to fill out and each of the 5 TMS sessions last 10 minutes.

OFFICIAL TITLE

An Investigation of Transcranial Magnetic Stimulation (TMS) for Trigeminal Neuralgia (TGN)

CONDITIONS	STUDY TYPE	ENROLLMENT (ESTIMATED)

Facial Pain	Interventional	51

INTERVENTION / TREATMENT

Device: TMS

Device: sham TMS coil

PHASE

Not Applicable

OTHER STUDY ID NUMBERS

19-371

STUDY START (ACTUAL)

August 1, 2020

PRIMARY COMPLETION (ESTIMATED)

February 2021

STUDY COMPLETION (ESTIMATED)

June 2021

Resource links provided by the National Library of Medicine

MedlinePlus (https://medlineplus.gov/) related topics: Trigeminal Neuralgia (https://medlineplus.gov/trigeminalneuralgia.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources:
Trigeminal Neuralgia (https://rarediseases.info.nih.gov/diseases/7805/trigeminal-neuralgia)
Chronic Graft Versus Host Disease (https://rarediseases.info.nih.gov/diseases/10964/chronic-graft-versus-host-disease)

Other U.S. FDA Resources (https://clinicaltrials.gov/ct2/info/fdalinks)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

STUDY CONTACT

STUDY CONTACT BACKUP

Name: Mark Witcher, MD, PhD
Phone Number: 540-224-5170
Email: mrwitcher@carilionclinic.org

Name: Mallory Blackwood, MS
Phone Number: 8047542825
Email: bmal@vt.edu

United States

Virginia Locations

Roanoke, Virginia, United States, 24014
Recruiting
Institute for Orthopedics and Neurosciences
Contact: Jordan Darden, PhD
540-981-7942 jadarden@carilionclinic.org

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://beta.clinicaltrials.gov/about-studies).

Eligibility Criteria

AGES ELIGIBLE FOR STUDY	ACCEPTS HEALTHY VOLUNTEERS	SEXES ELIGIBLE FOR STUDY
18 Years to 100 Years (Adult, Older Adult)	No	All

DESCRIPTION

Inclusion Criteria:

- Documented diagnosis of classic trigeminal neuralgia or persisten idiopathic facial pain
- Considered an appropriate candidate for surgical or stereotactic intervention - microvascular decompression or stereotactic radiosurgery- (includes factors such as overall health, chronic medication, comorbidities) and patient preference
- Between ages 18-100
- Able to participate in 5 consecutive TMS treatments
- Has at least 3 weeks between pre-op visit and scheduled date of surgery
- Able to provide consent and complete online questionnaires on their own

Exclusion Criteria:

- Multiple Sclerosis or trauma-related etiology of facial pain (i.e. secondary facial pain)
- contraindication to TMS, per device guidelines:

Metallic implant in or near head Implanted stimulator on or near head recent suicidal ideation history of epilepsy, stroke, or unexplained seizure

- Need for urgent/emergent surgical decompression.

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

DESIGN DETAILS

Primary Purpose: Treatment
Allocation: Randomized
Interventional Model: Parallel Assignment
Interventional Model Description: TMS, sham-TMS, and no treatment groups
Masking: Double
Masking Description: TMS and sham TMS treatment group participants and researchers will be blinded to which treatment the participant receives

NUMBER OF ARMS

3

ARMS AND INTERVENTIONS

Participant Group/Arm	Intervention/Treatment
Experimental: TMS treatment participants receive TMS treatment	Device: TMS Transcranial Magnetic Stimulation (TMS) is a noninvasive brain stimulation technique which produces short pulsatile magnetic fields (similar to that of an MRI) via two extracranial, figure 8-shaped electric coils which can induce a small, temporary, electric current in the brain currently approved and used for depression. Other Name: • TMS coil
Sham Comparator: sham TMS participants receive control TMS treatment	Device: sham TMS coil The sham TMS does cause some stimulation to the participant so that the participants get the sensation of treatment without any cortical excitation that TMS

	delivers. The sensation experienced is similar to the muscle twitching or finger tapping experienced by TMS participants.
No Intervention: non intervention control group	

What is the study measuring?

PRIMARY OUTCOME MEASURES

Outcome Measure	Measure Description	Time Frame
Changed Pain assessed by self reported measures: Short-form McGill Pain Questionnaire 2 (SF-MPQ-2)	The primary objective is to establish the effectiveness of TMS for COFP pain management in the interim period before surgery. This will be investigated by comparing the non-intervention group's self-reported pain to those who received TMS at several timepoints. Short-form McGill Pain Questionnaire 2 (SF-MPQ-2)will be used. The scale asks participants to identify their pain level across body areas and total from 0-10 (0 being none & 10 worst possible)	7 months

SECONDARY OUTCOME MEASURES

Outcome Measure	Measure Description	Time Frame
Length of altered pain	A secondary objective is to establish how long the effects of TMS last. This will be done by comparing self-reported pain scores prior to TMS, after TMS	7 months

	and at several timepoints thereafter in those who recieved the treatment. Short-form McGill Pain Questionnaire 2 (SF-MPQ-2) will be used. The scale asks participants to identify their pain level across body areas and total from 0-10 (0 being none & 10 worst possible)	

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

SPONSOR

Carilion Clinic

COLLABORATORS

No information provided

INVESTIGATORS

Principal Investigator: Mark Witcher, MD, PhD, Surgeon

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

GENERAL PUBLICATIONS

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

More Information

Terms related to this study

KEYWORDS PROVIDED BY MARK WITCHER, CARILION CLINIC

trigmenial neuralgia
Chronic orofacial pain

ADDITIONAL RELEVANT MeSH TERMS

Peripheral Nervous System Diseases
Neuromuscular Diseases
Nervous System Diseases
Pain
Neurologic Manifestations
Trigeminal Nerve Diseases
Facial Neuralgia
Facial Nerve Diseases
Mouth Diseases

Stomatognathic Diseases
Cranial Nerve Diseases
Trigeminal Neuralgia
Neuralgia
Facial Pain

Plan for Individual participant data (IPD)

PLAN TO SHARE INDIVIDUAL PARTICIPANT DATA (IPD)?

No

Drug and device information, study documents, and helpful links

STUDIES A U.S. FDA-REGULATED DRUG PRODUCT

No

STUDIES A U.S. FDA-REGULATED DEVICE PRODUCT

No

PRODUCT MANUFACTURED IN AND EXPORTED FROM THE U.S.

No