ClinicalTrials.gov Identifier: NCT05075707

Comparison Between Magnetic Field and Laser Therapy in Management of Trigeminal Neuralgia

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Last Updated: March 11, 2022

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
September 19, 2021	September 29, 2021	October 13, 2021

Study Record Updates

LAST UPDATE SUBMITTED THAT MET QC CRITERIA	LAST UPDATE POSTED	LAST VERIFIED
March 11, 2022	March 16, 2022	March 2022

Study Tab

Study Overview

Brief Summary:

Trigeminal neuralgia (TN) was defined by The International Association for the Study of Pain (IASP) as severe, sudden, usually unilateral, stabbing, brief, recurrent attacks of pain in one or more distributional branches of the trigeminal nerve. The purpose of the current study will to investigate the effect of Low level laser therapy versus electromagnetic therapy on diabetic trigeminal neuralgia pain intensity and amplitude of the compound muscle action potential of the masseter and temporalis muscles in diabetic TN patients.

OFFICIAL TITLE

Magnetic Field and Laser Therapy in Management of Diabetic Trigeminal Neuralgia

CONDITIONS	STUDY TYPE	ENROLLMENT (ACTUAL)
Trigeminal Neuralgia	Interventional	120

INTERVENTION / TREATMENT	PHASE	OTHER STUDY ID NUMBERS
Other: Electromagnetic therapy.	Not Applicable	magnetic and laser therapy

Other: Low level laser therapy (LLLT)

STUDY START (ACTUAL)	PRIMARY COMPLETION (ACTUAL)	STUDY COMPLETION (ACTUAL)
October 15, 2021	February 22, 2022	February 23, 2022

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)

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.

Egypt

Cairo, Egypt
AAA

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
25 Years to 45 Years (Adult)	No	All

DESCRIPTION

Inclusion Criteria:

- All participants will between the ages of 25 and 45, will of both sexes (male and female), diabetic type two patients with chronic trigeminal neuralgia, (from three to six months).
- Patients will awake, cooperative, and free of psychiatric issues (as determined by a psychologist) as well as difficulties resulting from orthopaedic or special sensory deficits.

Exclusion Criteria:

- Patients will ruled out if they developed TN due to a tumour, herpes zoster, or any other reason other than diabetes, such as significant coagulation dysfunction, cardiopulmonary dysfunction or previous invasive treatment (ethanol, radiofrequency, Gama-knife microvascular decompression, glycerinum injection).
- They will not have a previous disability in the face.

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
Masking: Single

NUMBER OF ARMS

3

ARMS AND INTERVENTIONS

Participant Group/Arm	Intervention/Treatment
No Intervention: control group Participants will receive the descriptive medication by neurologist	

Experimental: electromagnetic group Participants will receive the descriptive medication by neurologist in addition to electromagnetic therapy. Electromagnetic therapy will be applied for 20 min/session for three days each week for two months.	Other: Electromagnetic therapy. Electromagnetic therapy will be applied for 20 min/ session for (3 days/ week for two months) to the group intervention.
Experimental: low laser therapy group Participants will receive the descriptive medication by neurologist in addition to low laser therapy. Low laser therapy will be applied for 20 min/session for three days each week for two months.	Other: Low level laser therapy (LLLT) Low level laser therapy (LLLT) will be applied for 20 min/session laser scanner for three days each week for two months to the group intervention.

What is the study measuring?

PRIMARY OUTCOME MEASURES

Outcome Measure	Measure Description	Time Frame
Studies using electromyography and complex muscle action potentials	All patients' compound motor action potential amplitudes in the masseter and temporalis muscles will be evaluated before interventions.	at the beginning of the study

Studies using electromyography and complex muscle action potentials	All patients' compound motor action potential amplitudes in the masseter and temporalis muscles will be evaluated after two month of interventions.	by the end of successful two month of intervention
Visual analogue scale (VAS)	All the participants were instructed to express their pain by Visual analogue scale (VAS) before the interventions.	at the beginning of the study
Visual analogue scale (VAS)	All the participants were instructed to express their pain by Visual analogue scale (VAS) after two month of interventions.	by the end of successful two month of intervention

Collaborators and Investigators

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

SPONSOR

Delta University for Science and Technology

COLLABORATORS

No information provided

INVESTIGATORS

No information provided

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

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

Plan for Individual participant data (IPD)

PLAN TO SHARE INDIVIDUAL PARTICIPANT DATA (IPD)?

Yes

IPD PLAN DESCRIPTION

Individual participant data (IPD) will be available to other researchers after 12 month from publishing.

IPD SHARING TIME FRAME

After 12 month from publishing.

IPD SHARING SUPPORTING INFORMATION TYPE

Study Protocol

Statistical Analysis Plan (SAP)
Clinical Study Report (CSR)

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