A Comparative Study on the Effect of Vagus Nerve Stimulation on Trapezius Trigger Points

May 2025

NCT Number: [NCT ID not yet assigned]

Study Identification

- Unique Protocol ID: BAU-MA25
- Brief Title: Effect of Vagus Nerve Stimulation on Trapezius Trigger Points
- Official Title: A Comparative Study on the Effect of Vagus Nerve Stimulation and Ischemic Compression on Trapezius Trigger Points
- Secondary ID: None

Study Status

- Record Verification Date: December 2024
- Overall Status: Active, not recruiting
- Study Start Date: January 15, 2025
- Primary Completion Date: May 15, 2025
- Study Completion Date: June 25, 2025 (Anticipated)

Sponsor/Collaborators

- Sponsor: None
- Responsible Party: Principal Investigator
- Investigator: Shahla Hasanilar Ansaroudi, MSc, Physiotherapy and Rehabilitation, Bahçesehir University
- Collaborators:
  - Prof. Dr. Hasan Kerem Alptekin, Bahçesehir University
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Oversight

- U.S. FDA-regulated Drug/Device/IND/IDE: No
- Human Subjects Review:
  - Board Status: Approved
  - Approval Number: 61351342/020-667

- Board Name: Üsküdar University Ethical Committee
- Board Affiliation: Bahçesehir University
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Study Description

Brief Summary

This randomized controlled trial aims to evaluate the efficacy of non-invasive vagus nerve stimulation (nVNS) compared to ischemic compression (trigger point massage) and exercise in treating trigger points in the upper trapezius muscle. Ninety participants aged 18-55 with at least two trigger points were randomly assigned to three groups: nVNS, ischemic compression, or exercise (control). Interventions were administered over 10 sessions (3 times per week). Outcomes included pain intensity (Visual Analog Scale, VAS), trigger point number, pain pressure threshold (algometer), neck function (Copenhagen Neck Functional Disability Scale, KBFÖS), well-being (WHO-5 Well-Being Index), and functional mobility. The nVNS group demonstrated statistically significant improvements in all outcomes compared to the other groups ($p < 0.05$).

Detailed Description

Myofascial pain syndrome (MPS) is characterized by trigger points-hyperirritable spots in skeletal muscle associated with pain, stiffness, and reduced function. The upper trapezius muscle is a common site for trigger points, contributing to neck pain and disability. Traditional treatments include ischemic compression and exercise, but non-invasive vagus nerve stimulation (nVNS) has emerged as a promising modality due to its ability to modulate pain pathways and autonomic function.

This study investigates whether nVNS is more effective than ischemic compression or exercise in reducing pain and improving function in patients with trapezius trigger points. Participants were randomized into three groups ($n = 30$ each):

- nVNS Group: Received auricular vagus nerve stimulation (10 Hz, 300 μs, 20 minutes per session) using a non-invasive device adjusted to patient tolerance.
- Ischemic Compression Group: Received trigger point massage (30-90 seconds per point, 3 times per week).
- Exercise Group (Control): Performed isometric neck exercises, upper trapezius stretching, and chin tuck exercises.

Assessments were conducted pre- and post-intervention using validated tools. The nVNS group showed superior outcomes in pain reduction, trigger point resolution, pain threshold, neck function, and well-being ($p < 0.05$). Additional benefits included improved sleep quality, reduced stress, and enhanced mood, with no serious adverse events reported.

Keywords: Trigger Points, Vagus Nerve, Auricular Vagus Nerve Stimulation, Parasympathetic System, Ischemic Massage

Study Design

- Study Type: Interventional
- Primary Purpose: Treatment
- Study Phase: Not Applicable (Non-drug intervention)
- Interventional Study Model: Parallel Assignment
- Number of Arms: 3
- Masking: Single (Outcomes Assessor)
- Allocation: Randomized • Enrollment: 90 (Actual)

Arms and Interventions

Arm 1: Vagus Nerve Stimulation (nVNS)

- Intervention Type: Device
- Description: Non-invasive auricular vagus nerve stimulation delivered bilaterally to the concha and tragus using a TENS-based device (10 Hz, 300 μs, 20 minutes, 10 sessions over 4 weeks). Intensity was adjusted to patient comfort.
- Intervention Name: Auricular Vagus Nerve Stimulation

Arm 2: Ischemic Compression

- Intervention Type: Procedure
- Description: Manual trigger point massage (ischemic compression) applied to trapezius trigger points for 30-90 seconds per point, 3 times per week for 10 sessions.
- Intervention Name: Trigger Point Massage

Arm 3: Exercise (Control)

- Intervention Type: Behavioral
- Description: Standardized exercise program including isometric neck exercises, upper trapezius stretching, and chin tuck exercises, performed 3 times per week for 10 sessions.
- Intervention Name: Exercise Program

Outcome Measures

Primary Outcome Measures

1. Pain Intensity (VAS)
    - Description: Measured using the Visual Analog Scale (0-10), where 0 indicates no pain and 10 indicates worst possible pain.
    - Time Frame: Baseline and post-intervention (week 4).
2. Number of Trigger Points
    - Description: Count of active and latent trigger points in the upper trapezius muscle, assessed by palpation.
    - Time Frame: Baseline and post-intervention (week 4).
3. Pain Pressure Threshold (Algometer)
    - Description: Measured using a digital algometer (kg/cm^2) at trigger point sites to assess pain sensitivity.
    - Time Frame: Baseline and post-intervention (week 4).

Secondary Outcome Measures

1. Neck Function (KBFÖS)
    - Description: Assessed using the Copenhagen Neck Functional Disability Scale, evaluating neck-related disability (0-30, higher scores indicate greater disability).
    - Time Frame: Baseline and post-intervention (week 4).
2. Well-Being (WHO-5)
    - Description: Measured using the WHO-5 Well-Being Index, a 5-item scale (0-25, higher scores indicate better well-being).
    - Time Frame: Baseline and post-intervention (week 4).
3. Functional Mobility
    - Description: Assessed through clinical tests of neck range of motion and mobility tasks.
    - Time Frame: Baseline and post-intervention (week 4).

Eligibility Criteria

- Ages Eligible for Study: 18 Years to 55 Years (Adult)

- Sexes Eligible for Study: All
- Accepts Healthy Volunteers: No

Inclusion Criteria

- Age 18-55 years.
- Presence of at least two trigger points (active or latent) in the upper trapezius muscle, confirmed by palpation.
- Ability to provide informed consent.

Exclusion Criteria

- History of cervical spine surgery or trauma.
- Neurological disorders (e.g., epilepsy, stroke).
- Pregnancy or breastfeeding.
- Use of pacemakers or other implanted electrical devices.
- Active infection or skin lesions at the stimulation site.
- Recent use of botulinum toxin or other trigger point injections.

Contacts/Locations

Contacts

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Locations

- Facility: Bahçesehir University, Physiotherapy and Rehabilitation
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- Facility: Beykent University Hospital
    - City: Istanbul, Turkey
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Study Results

- Results Submission: Not applicable (study not yet finished).
- Results Point of Contact: Shahla Hasanilar Ansaroudi, MSc, shahla.hassanilar@bahcesehir.edu.tr