Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation the effects of Massage Gun on pain and range of mation in the upper Trapezius myofascial trigger point, a randomized clinical Trial

Protocol summary

Study aim
Investigating the therapeutic effect of massage gun in a patient with pain and limitation of neck movement caused by muscle trigger points in the upper trapezius muscle

Design
There are two study groups (massage gun and acupuncture), with 20 patients in each (total 40 patient). Study is blinded, and random assignment is done by using a random-numbers-table

Settings and conduct
The study is carried out in the sports-medicine-clinic of Taleghani-Hospital, Tehran Consent is obtained and patients fill out the NPQ-questionnaire. The measurement is done while sitting on a chair, and the treatment is done on the bed(prone position) Statistician and measurer of treatment parameters, take the information as a code

Participants/Inclusion and exclusion criteria
Age18_65 years Presence of a clinically relevant painful point Not suffering from major depression, fibromyalgia or chronic fatigue syndrome Not suffering from life-threatening metabolic diseases (diabetes, cardiovascular diseases, neurological diseases, coagulation status) no pregnancy No history of head, neck or shoulder surgery BMI below 30 kg/m2

Intervention groups
Patients are divided into two treatment groups and are treated with massage gun or acupuncture. Massage gun treatment sessions: with small round ball, at low-speed (level-1) for 5 minutes (massage for 5 seconds at each point, then move to the next point and repeating the process) Acupuncture treatment sessions: performed with 25 mm disposable steel needles (0.25 mm thickness) of Huanqiao-Company, and the number of needles per session is 3 to 10. 3 treatment sessions are performed, with a minimum interval of two days, and all is done at maximum in two weeks.

Main outcome variables
pain and range of motion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240811062721N1**
Registration date: **2025-02-07, 1403/11/19**
Registration timing: **retrospective**

Last update: **2025-02-07, 1403/11/19**
Update count: **0**

Registration date
2025-02-07, 1403/11/19

Registrant information

Name
Shiva Dehghan Ghahfarokhi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2243 2560

Email address
shiva2010med@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-08-21, 1403/05/31

Expected recruitment end date
2024-10-22, 1403/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation the effects of Massage Gun on pain and range of mation in the upper Trapezius myofascial trigger point, a randomized clinical Trial

Public title
Evaluation the effects of a Massage device on muscle spasm in neck and shoulder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
all patient with shoulder and neck pain

Exclusion criteria:
previous shoulder and neck surgery cervical radiculopathy, osteoarthritis, myopathy, major depression, Fibromyalgia or chronic fatigue syndrome Life-threatening metabolic diseases (such as diabetes mellitus, Cardiovascular, neurological disease, coagulative state) Pregnancy BMI more than 30 kg/m2 no cooperation

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to achieve bias and comparability between the two groups, a generation method is used to assign individuals to the case and control groups. The method used in this study is the generation of random numbers. In this way, a number is generated randomly for each participant in the study. After generating random numbers with the help of statistical software, a threshold value, for example 0.5, is determined to determine whether the individual is assigned to the control or the case group. For example, if the random number assigned to the individual is less than 0.5. In order to assign individuals to groups, the participants are distributed to the control groups and examined to have an identification process of the participants in each group. If the absence between the two groups is severe, the participants are re-randomized. SPSS software is used to generate random numbers. To conduct random assignment and assign participants to intervention and control groups in this study, the following steps were taken using SPSS: 1. **Creating New Variables**: A new variable named "Group" was created in the SPSS data file to determine the intervention and control groups. 2. **Generating Random Numbers**: The `RV.UNIFORM(0,1)` function was used to generate random numbers between 0 and 1 for each participant. This function can be executed in SPSS by going to the `Transform` menu and selecting `Compute Variable`. 3. **Defining the Threshold**: A threshold value of 0.5 was set. The random numbers generated for each participant were compared to this threshold. 4. **Assigning Groups**: If the random number generated for a participant was less than 0.5, they were assigned to the intervention group (e.g., value of 1); otherwise, they were assigned to the control group (e.g., value of 0). This assignment was implemented using the following SPSS command: ```plaintext IF (RV.UNIFORM(0,1) < 0.5) Group = 1. ELSE Group = 0. EXECUTE. ``` 5. **Checking Randomization Distribution**: After randomization, the distribution of participants in the intervention and control groups was checked to ensure the randomization process had resulted in a balanced representation of participants in each group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The assessment before and after the treatment is done by a sports medicine resident who is not involved in the treatment, and the information collection form, does not include written information on the treatment method. The analysis is done by Amarist and the information of the two groups is delivered to Amarist with a code for evaluation.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of medical sciences

Street address
Araabi st. Daneshjou Blvd. Velenjak. Taleghani hospital

City
Tehran

Province
Tehran

Postal code
1985711151

Approval date
2024-07-31, 1403/05/10

Ethics committee reference number
IR.SBMU.MSP.REC.1403.237

Health conditions studied

1

Description of health condition studied
muscle spasm
ICD-10 code
M62.838
ICD-10 code description
Other muscle spasm

Primary outcomes

1

Description
pain
Timepoint
baseline and after therapeutic sessions
Method of measurement
Visual Analogue Scale

2

Description
Park Northwick Questionnaire score
Timepoint
baseline and after therapeutic sessions
Method of measurement
Park Northwick Questionnaire

3

Description
neck Range of motion
Timepoint
baseline and after therapeutic sessions
Method of measurement
protractor

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Three treatment sessions with a Urikar massage gun by the therapist and each session lasts for 5 minutes at a low speed (level 1 equivalent to 30-40 Hz) in the location of muscle trigger points in the upper trapezius muscle
Category
Treatment - Devices

2

Description
Three sessions of acupuncture treatment for 10 minutes each session using 3 to 10 25 x 25 Huanqiu needles in the location of muscle trigger points in the upper trapezius muscle
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Shiva Dehghan Ghahfarokhi
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Daneshjou Blvd. Velenjak
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1985717443
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urm@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

شیوا دهقان قهفرخی

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Sport Medicine

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Person responsible for scientific inquiries

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Position

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available