Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

English: Comparison of The Immediate Effects of Electroacupuncture and Laseracupuncture on Pain and Dysfunction Following Chronic Myofascial Neck Pain

Protocol summary

Study aim

Comparison of the immediate effects of two methods of electro-acupuncture and laser-acupuncture on pain reduction, increase in range of motion, increase in pain pressure threshold and disability reduction in patients with chronic myofascial neck pain before, after and one week after intervention.

Design

Randomized(Balanced block Randomization) ,Control ,Single Blind (assessor blinding)Trial

Settings and conduct

By advertisement in TUMS, female students with neck pain will be invited to come to the Physiotherapy Clinic of the Faculty of Rehabilitation. At first, the Inclusion criteria and exclusion criteria of the study will be assess in all the clients and the clients who have all inclusion criteria will participate to the research voluntarily after completing the consent form.secondly, patients will randomize with the Balance Block method. In this study, the assessor is blind.

Participants/Inclusion and exclusion criteria

Girls aged 18 to 35 years with more than 12 weeks of pain in the neck with a pain score of more than 3, based on the VAS scale, without a history of negative response to needle or vascular disease and malignancy that are acupuncture contradictions.

Intervention groups

1) Electro-acupuncture group The intervention in this group involves electrical stimulation through the needle at the acupuncture points. 2) Laser-acupuncture group Interventions in this group include laser radiation at the acupuncture points . 3) control group The intervention in this group consists of sham laser acupuncture. The patient's condition and acupuncture points are similar to the laser-acupuncture group, with the exception that the laser probe is used off.

Main outcome variables

neck pain (based on VAS scale), cervical range of motion (based on goniometer), pain pressure threshold in cervical region (based on algometer) and disability (based on Neck disability index)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190104042229N1**
Registration date: **2019-07-14, 1398/04/23**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-14, 1398/04/23**
Update count: **0**

Registration date

2019-07-14, 1398/04/23

Registrant information

Name

Atefe Bahadori Bozchelooee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4420 6707

Email address

bahadori_atefe@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-20, 1398/02/30

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

English: Comparison of The Immediate Effects of Electroacupuncture and Laseracupuncture on Pain and Dysfunction Following Chronic Myofascial Neck Pain

Public title

Acupuncture in Neck Pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 to 35 years old Having more than 12 weeks of history of Myofascial Neck Pain Having pain above 3 is based on the VAS scale, which is considered as moderate pain Satisfaction to participate in the research project "Comparison of The Immediate Effects of Electroacupuncture and Laseracupuncture on Pain and Dysfunction Following Chronic Myofascial Neck Pain"

Exclusion criteria:

History of Injection,Dry needling and Acupuncture In last month History of Muscular Disease such as Fibromyalgia and myopathy History of Neurological Disorders Neck Discopathy and Radiculopathy History of Neck Surgery History of Negative response to Acupuncture or Dry needling Needle Phobia Malignancy and Patients susceptible to infection Having vascular diseases and using anticoagulants pregnancy History of epilepsy or seizure Diabetes During menstruation

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced Block Randomizatin According to the study of three groups in this RCT, six blocks are used to randomize each group , group A, B, C Then, we write the different modes of the six blocks of the AABBCC and place it in the package and the first patient in the study will select one of the packets. For example: ABABCC In this case, the first patient enters group A and the rest of the patients entering the study will be placed in subsequent groups, respectively.

Blinding (investigator's opinion)

Single blinded

Blinding description

Single Blind Which assessor is blind about the type of intervention in each group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Faculty of Nursing and Midwifery, Faculty of Rehabilitation, Tehran University o

Street address

No 72 ,Sayyar Ave ,Rahimi street, 1th Sadeghie Square

City

Tehran

Province

Tehran

Postal code

1451863463

Approval date

2019-04-28, 1398/02/08

Ethics committee reference number

IR.TUMS.FNM.REC.1398.005

Health conditions studied

1

Description of health condition studied

Neck pain

ICD-10 code

M54.2

ICD-10 code description

Cervicalgia

2

Description of health condition studied

Myofascial pain

ICD-10 code

S16

ICD-10 code description

Injury of muscle, fascia and tendon at neck level

Primary outcomes

1

Description

The pain score of people based on the Visual Analog scale

Timepoint

Before the intervention, immediately after the intervention and one week after the intervention

Method of measurement
Visual Analog scale

2

Description
Pain pressure threshold
Timepoint
Before the intervention, immediately after the intervention and one week after the intervention
Method of measurement
pressure algometer

3

Description
Disability
Timepoint
Before the intervention, immediately after the intervention and one week after the intervention
Method of measurement
Neck Disability index Questionnaire

4

Description
cervical range of motion
Timepoint
Before the intervention, immediately after the intervention and one week after the intervention
Method of measurement
Goniometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Electroacupuncture:In this group, 8 acupuncture points are introduced to reduce the myofscial neck pain. The needle is applied and the electrical current is connected to the needles with specific therapeutic parameters and exposed to electrical stimulation for 20 minutes.
Category
Treatment - Devices

2

Description
Intervention group: Laseracupuncture:In this group, low-power laser waves with specific parameters will radiate at 8 acupuncture points which is similar to the first group.
Category
Treatment - Devices

3

Description
Control group: Sham Laser-acupuncture:in This group the off laser probe will be use at the similar points of the last two groups .
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran University of Medical Science
Full name of responsible person
Atefe Bahadori
Street address
Śafi Alishah,Pich-e-Shemiran,Enghelab St,Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
dr Seyyed Mohsen Mir
Street address
Pich-e-Shemiran, Enghelab st, Tehran
City
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Province
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Postal code
1148956111
Phone
+98 21 7763 6041
Email
rehabilitation@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Atefe Bahadori Bozchelooee

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Master student

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Reproducible data includes general information about patients, their medical conditions and factors measured before and after their intervention, and personal information of the patients will not be published.

When the data will become available and for how long

6 months after results publication

To whom data/document is available

academic researchers

Under which criteria data/document could be used

The data will sent to valid academic emails for only studying and reviewing the results and will not allow any

analysis or printing.

From where data/document is obtainable

Applicants can request to receive information by sending an email to the following e-mail address bahadori_atefe@yahoo.com

What processes are involved for a request to access data/document

The applicant can declare an application by sending a message from a valid academic email, and the requested information will be sent within a maximum of two weeks by email.

Comments