Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

The Investigation of the Effects of Deep Dry Needling into Trigger Points of Temporalis, Sternocleidomastoid and Upper Trapezius on Females with Episodic Tension Type Headache

Protocol summary

Study aim

The aim of this study is to investigate the effects of deep dry needling into trigger points of Temporalis, Sternocleidomastoid and upper Trapezius muscles in women with episodic tension type headache.

Design

A blocking Randomized,Single- blinded, controlled clinical trial with a parallel group design including 24 patients

Settings and conduct

Patients with headache in the Headache Center of Sina Hospital will be selected and signing the informed consent, will be instructed to record the headache parameters over 4 weeks. They will be assessed and will be randomly assigned to control and intervention groups. The assessment will be done before treatment and 1 month after treatment. All stages will be carried out at the School of Rehabilitation Sciences, Iran University of Medical Sciences .

Participants/Inclusion and exclusion criteria

Inclusion criteria : Having episodic tension type headache(ETTH) based on international classification of headache (ICHD-3) ; Having at least one active trigger point in one of the given muscles : Temporalis(Left or Right), upper Trapezius(Left or Right) , Sternocleidomastoid (Left or Right). Exclusion criteria :Having other primary or secondary headaches;History of neck injury; Acute depression ;Cervical radiculopathy ;History of surgery in neck or shoulder ; Pregnant women.

Intervention groups

Intervention group: The patients will receive one session of deep dry needling at one trigger point (active or latent) in the temporalis, sternocleidomastoid, and upper trapezius muscles in both sides. Then ,they will receive passive stretching of the aforementioned muscles in both sides. Control group: The patients will receive only one session of passive stretching similar to the intervention group.

Main outcome variables

Headache intensity ;Headache frequency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200129046302N1**
Registration date: **2020-02-26, 1398/12/07**
Registration timing: **retrospective**

Last update: **2020-02-26, 1398/12/07**
Update count: **0**

Registration date

2020-02-26, 1398/12/07

Registrant information

Name

Soheil Mansour Sohani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 8051

Email address

mansorsohani.s@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-06, 1397/12/15

Expected recruitment end date

2019-09-20, 1398/06/29

Actual recruitment start date

2019-03-15, 1397/12/24

Actual recruitment end date
2019-10-21, 1398/07/29
Trial completion date
2019-10-21, 1398/07/29

Scientific title
The Investigation of the Effects of Deep Dry Needling into Trigger Points of Temporalis, Sternocleidomastoid and Upper Trapezius on Females with Episodic Tension Type Headache

Public title
The Investigation of the Effects of Deep Dry Needling in Females with Episodic Tension Type Headache
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having a diagnosis of Episodic tension type headache (ETTH) based on the International Classification of Headache Disorders(ICHD-3) Having at least one active trigger point in one of the given muscles : Temporalis(Left or Right), upper Trapezius(Left or Right) , Sternocleidomastoid (Left or Right)
Exclusion criteria:
Having primary or secondary headaches History of neck injury Acute depression History of surgery in neck and shoulder Cervical radiculopathy History of dry needling treatment in the neck or head for the past six months Pregnant women
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **26**
Actual sample size reached: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned to the intervention or control groups. The random allocation method of these two groups will be block randomization. Block size will comprise 6 persons (overall there will be 4 blocks). Random allocation software will be used to determine the sequence of patient's allocation to each group.
Blinding (investigator's opinion)
Single blinded
Blinding description
Pre-treatment,post-treatment assessments will be performed by the physiotherapist who is supposed to be blinded to the allocation concealment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
•Ethics committee of Iran university of medical sciences
Street address
Iran university of medical sciences, next to Milad tower, Hemmat highway
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2019-02-23, 1397/12/04
Ethics committee reference number
IR.IUMS.REC.1398.048

Health conditions studied

1

Description of health condition studied
Episodic tension type headache
ICD-10 code
G44.21
ICD-10 code description
Episodic tension-type headache

Primary outcomes

1

Description
Headache intensity
Timepoint
Headache intensity assessment at the baseline(4 weeks before intervention) and 4 weeks after intervention
Method of measurement
Visual analogue scale

2

Description
Headache frequency
Timepoint
Headache frequency assessment at the baseline(4 weeks before intervention) and 4 weeks after intervention
Method of measurement
The number of days with headache within 4 weeks

Secondary outcomes

1

Description
Neck range of motion
Timepoint
At the beginning of the intervention , immediately , 2 and 4 weeks after intervention
Method of measurement
Goniometer

2

Description
Mouth opening range of motion
Timepoint
At the beginning of the intervention , immediately , 2 and 4 weeks after intervention
Method of measurement
Ruler

3

Description
Trigger points pain pressure threshold
Timepoint
At the beginning of the intervention , immediately , 2 and 4 weeks after intervention
Method of measurement
Algometer

4

Description
Quality of life
Timepoint
before intervention and 4weeks after intervention
Method of measurement
SF-36 Quality of life Questionnaire

5

Description
Sleep quality
Timepoint
before intervention and 4weeks after intervention
Method of measurement
Pittsburgh sleep quality questionnaire

Intervention groups

1

Description
Intervention group:Single session treatment with deep dry needling(Dongbang model, South Korea, 50*0/3 mm)in the trigger points of the Temporalis, Sternocleidomastoid and upper Trapezius muscles in both sides(after obtaining one local twitch response ,the needle will be inserted 8 times with fast in fast out technique)following with passive stretching(4 seconds of stretching and 8 seconds of rest , this cycle will be repeated 3 times for each muscle).
Category
Rehabilitation

2

Description
Control group: Single session of passive stretching in the Temporalis, Sternocleidomastoid and upper Trapezius muscles in both sides (4 seconds of stretching and 8 seconds of rest , this cycle will be repeated 3 times for each muscle).
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Headache center of Sina Hospital
Full name of responsible person
Dr.Mansoure Togha
Street address
Imam Khomeini St., Hassan Abad Sq., Sina Hospital
City
Tehran
Province
Tehran
Postal code
١١٣٦٧٤٦٩١١
Phone
+98 21 6634 8500
Email
hosp_sina@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Seyyed Abbas Motevalian
Street address
Iran university of medical sciences,Milad tower,Hemmat highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2503
Email
motevalian.a@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Faezeh Abaschian
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
No18.Shahid Ahmadian Ave,Torkamenstan Str.Motahari Str
City
Tehran
Province
Tehran
Postal code
23478-87688
Phone
+98 21 8844 6048
Email
faezeh_abaschian@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Soheil Mansour Sohani
Position
Assiatant professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
School of Rehabilitation Sciences, Iran University of Medical Sciences, Maddadkaran St., Shahid Nazari St., Mother Square, Mirdamad Blvd
City
Tehran
Province
Tehran
Postal code
۱۳۴۸۷ - ۱۵۴۵۹
Phone
+98 21 2222 2059
Email
mansorsohani.s@ums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Soheil Mansour Sohani
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
School of Rehabilitation Sciences, Iran University of Medical Sciences, Maddadkaran St., Shahid Nazari St., Mother Square, Mirdamad Blvd
City
Tehran
Province
Tehran
Postal code
۱۳۴۸۷ - ۱۵۴۵۹
Phone
+98 21 2222 2059
Email
mansorsohani.s@ums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
all data will be shared after unidentified persons.
When the data will become available and for how long
accessibility will be 6 months after printing the result.
To whom data/document is available
all researchers and scientists, working in academic and scientific institutions, can access to data.
Under which criteria data/document could be used
Using of data is only possible by mentioning the name

and organizational affiliation of the correspond and co-author of the project and the published article.

From where data/document is obtainable

faezeh_abaschian@yahoo.com

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

If data is used in scientific and therapeutic activities, information will be provided within 2 weeks.

Comments