Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jun 2026

comparison between dry needling for suboccipital, levator scapula, upper trapezius, masseter, sternocleidomastoid, splenius capitis and cervicis, frontalis and temporalis muscles and sham dry needling on pain and active craniocervical range of motion in people with episodic tension-type headache

Protocol summary

Study aim
The effect of dry needling on pain, active range of motion of craniocervical, disability and headache frequency in patients with episodic tension type headache.

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, the number of patients in the pilot study is determined. Block balanced randomization will be used for randomization.

Settings and conduct
Patients undergo six sessions of treatment in Orthopedic Clinic, Faculty of Rehabilitation, University of Iran after a neurologist diagnoses a tension type headache. Assessments will be performed before treatment and one week after treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People diagnosed with an episodic tension-type headache based on the third edition of the International classification of Headache Disorders; age range of 20 to 50 years; With moderate pain that has at least one active trigger point in the target muscles. Exclusion criteria: Fear of needles, pregnant women or women with infants, cancer patients, infectious and systemic diseases, any changes in corticosteroids, absence of two or more sessions, history of other primary headaches, history of head, neck, or shoulder surgery; history of radiculopathy and other orthopedic neck injuries in the past year.

Intervention groups
treatment group: Six sessions dry needling for suboccipital, levator scapula, upper trapezius, masseter, sternocleidomastoid, splenius capitis and cervicis, temporalis and frontalis muscles In addition to basic treatment includes posture correction exercises and awareness of the nature and management of the disease. control group: Six sessions of sham treatment with basic treatment.

Main outcome variables
Pain intensity, craniocervical range of motion, functional disability

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210706051807N1**
Registration date: **2022-03-29, 1401/01/09**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-29, 1401/01/09**
Update count: **0**

Registration date
2022-03-29, 1401/01/09

Registrant information

Name
alireza gandomidokht

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-22, 1400/09/01
Expected recruitment end date
2022-06-21, 1401/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
comparison between dry needling for suboccipital, levator scapula, upper trapezius, masseter, sternocleidomastoid, splenius capitis and cervicis, frontalis and temporalis muscles and sham dry needling on pain and active craniocervical range of motion in people with episodic tension-type headache

Public title
Effect of dry needling on pain and active craniocervical range of motion in patients with tension-type headache.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Men and women between 20 and 50 years age Having a diagnosis of CTTH based on the International Classification of Headache Disorders, 3rd edition Having at least one active trigger point in each of the muscles of the sub occipital, sternocleidomastoid, upper trapezius, temporalis, levator scapula, masseter, frontalis and splenius cervicis and capitis Moderate pain intensity from 30 to 60 based on visual Analog scale
Exclusion criteria:
Fear of needles Any change in the dose or type of medication taken Absence of two consecutive sessions or more History of surgery in head, neck, and shoulder Pregnant woman and woman with infant People with cancer, infectious diseases or systemic diseases History of involvement with other types of primary headaches History of neck radiculopathy and other orthopedic neck injuries (including fractures, facet joint syndrome, etc.) in the past year.
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomized to an experimental group (dry needling and standard physical therapy) or a control group (sham dry needling and standard physical therapy) using the block balanced randomization with an allocation ratio of 1:1. The random allocation sequence will be created by a researcher not involved in the assessments or interventions. The random allocation method consists of four-letter blocks made of 2 letters; A and B (A letter shows dry needling and standard physical therapy and letter B indicates sham dry needling and standard physical therapy). Then, randomization letters will be placed in sequentially numbered opaque sealed envelopes. The treatment will be performed according to the letter in each envelope.
Blinding (investigator's opinion)
Double blinded
Blinding description
Two people will do assessment and treatment; the assessor will be blind to the allocation concealment, and participants will be blind to the actual treatment or control group. Both the treatment group and the control group receive primary treatment, including exercise and knowledge of the nature and management of the disease. The only difference between the two groups is the application of the needle subcutaneously in a location farther away from the marked points. The patient in the control group is placed in a real dry hand, and the same type of needle is used.
Placebo
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
No.19, Rabiei hashemi alley, Ahmadisakha street, Qazvin avenue, Gomrok town
City
Tehran
Province
Tehran
Postal code
1337899484
Approval date
2021-06-29, 1400/04/08
Ethics committee reference number
IR.IUMS.REC.1400.301

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

pain intensity according to visual analog scale

Timepoint

before intervention and 1 week after end of intervention

Method of measurement

Numeric Pain Rating Scale

2

Description

Active range of motion of craniocervical vertebrae with manual goniometer

Timepoint

before intervention and 1 week after end of intervention

Method of measurement

Manual goniometer

Secondary outcomes

1

Description

functional disability according to neck disability index

Timepoint

Before treatment and one week after treatment

Method of measurement

Neck disability index

2

Description

frequency of headache

Timepoint

Before treatment and one week after treatment

Method of measurement

Record days with headaches in a diary

3

Description

record the Dry needling side effect

Timepoint

Before treatment and one week after treatment

Method of measurement

record the Dry needling side effect

Intervention groups

1

Description

Intervention group: Dry needling treatment is performed by a physiotherapist who has been trained in this field and has three years of experience working with patients with musculoskeletal problems. In this study, a needle with a length of 3 cm and a diameter of 0.25, Tony model will be used. To perform a dry needling for the Temporalis, Frontalis and Masseter muscles, the patient is placed in a supine position, and after detecting the trigger points of the muscles by flat palpation with the non-dominant hand, the needle will enter the muscles perpendicular to the skin by the dominant hand. The needle will be moved inside these muscles by flexion and extension movements of the wrist by pistoning method. To perform a dry needling in the upper trapezius muscle, the patient sleeps prone. In this position, the therapist finds the active trigger points of this muscle by pincer palpation with the non-dominant hand, and then the therapist inserts the needle into the muscle with his dominant hand and moves the needle towards the fingers of his non-dominant hand. In this position, with flexion and extension movements of wrist, the therapist moves the needle into the muscle. Side position is used for Dry needling in Levator scapula and Splenius cervicis and capitis muscles. In this situation, the therapist finds the trigger points of these muscles by pincer palpation with the non-dominant hand and then inserts the needle into these muscles with the help of the dominant hand. For the upper part of the Levator scapula muscle, the needle enters the muscle perpendicular to the skin, and for the lower part of this muscle, the needle enters the muscle in the outward and distal direction, towards the upper angle of the scapula. For the splenius capitis muscle, the needle enters inward and distally toward the fingers of non-dominant hand. For the cervical splenius muscle, the needle will be inserted perpendicular to the skin in a backward-forward direction. For sub occipital muscle dry needling in the prone position, the therapist inserts the needle perpendicular into the skin between the transverse process of the atlas vertebra and the spinous process of the second cervical vertebra. The direction of the needle is towards the eye on the opposite side. The treatment is continued until it is no longer LTR taken from the muscles. After taking the last LTR, the needle stays in place for 20 minutes, and after removing the needle, the exit point of the needle will be compressed for 60 seconds. Treatment will take six sessions, two weeks and three sessions a week. As a basic treatment, patients will receive exercises to improve posture and education to be aware of the nature of the disease and how to manage it.

Category

Treatment - Other

2

Description

Control group: For Sham dry needling, the patient is placed in the position of a real dry needling and the same type of needle is used. The difference is that the needle is applied subcutaneously in a place farther from the marked points and After 20 minutes, remove the needle from the tissue and squeeze the area for 60 seconds. Treatment will take six sessions, two weeks and three sessions a week. As a basic treatment, patients will

receive exercises to improve posture and education to be aware of the nature of the disease and how to manage it.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthopedic Clinic of the School of Rehabilitation of Iran University of Medical Science

Full name of responsible person

Alireza Gandomidokht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Abbas Motavlian

Street address

Tehran, Hemat Highway next to Milad Tower

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adminsite@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

Alireza Gandomi Dokht

Position

master student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

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Latest degree

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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)
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
Yes - There is a plan to make this available

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
Individual Participant Data: all collected deidentified IPD

When the data will become available and for how long
starting 6 months after publication

To whom data/document is available
people working in academic institutions

Under which criteria data/document could be used
using for Supplementary study

From where data/document is obtainable
e-mail address : gandomidokht.a@iums.ac.ir

What processes are involved for a request to access data/document
name, address, position, title of study and protocol of study

Comments