Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

The effects of treating myofascial trigger points of neck using the techniques of dry needling and soft tissue release on the clinical feature of patients with migraine headache

Protocol summary

Study aim

The effect of trigger point therapy with dry needling and soft tissue release Techniques on clinical indexes of migraine headache patients

Design

Sixty migraine patients who are referred to the Neurology Clinic of Shiraz Medical Sciences Hospital are selected. The participants are randomly divided into three groups of control, DN and STR.

Settings and conduct

Migraine patients are evaluated for the presence of TRPs in UT, suboccipital, and SCM muscles. In the presence of TRPs in these muscles, subjects are assigned to three groups of control, DN and STR according to block randomization. The two-blind study will be conducted in such a way that people are assigned to groups and patients are evaluated by people who are unaware. Treatment is provided by a specialist physiotherapist and evaluated by a collaborator.

Participants/Inclusion and exclusion criteria

Inclusion: 1- Selection of patients according to International Headache Society criteria by neurologist . 2 - Active trigger points in the upper trapezius, sternocleidomastoid and suboccipital muscles. Exclusion: Cervical disc herniation, unusual migraine, pregnant subjects, and patients have contraindication for needling.

Intervention groups

Dry needling (DN): It is used on the trigger point (TRP) in the UT, SCM and suboccipital muscles. The needle is applied for three sessions. Soft Tissue Release (STR): It is included SCM muscle TRP therapy, suboccipital muscle inhibition, UT muscle TRP therapy, long axis longitudinal stretch, bilateral-lateral stretch. Patients receive each technique with repeated 5 times for 6 days. Control group: After the trigger points are determined, the therapist applied soft and superficial massage on the involved muscles.

Main outcome variables

1. Pain intensity 2. Pressure pain threshold 3.Muscle thickness 4.Disability Index 5.Cervical range of motions measurement 6-Headache parameters

General information

Reason for update

Since our study is prospective and unfortunately the starting date of the sample entry was incorrectly 2017 instead of 2018,we made the corrections.

Acronym

DNSTR

IRCT registration information

IRCT registration number: **IRCT20171219037956N1**
Registration date: **2018-02-11, 1396/11/22**
Registration timing: **prospective**

Last update: **2020-01-02, 1398/10/12**
Update count: **1**

Registration date

2018-02-11, 1396/11/22

Registrant information

Name

tahere rezaeian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-02, 1397/01/13

Expected recruitment end date

2018-07-21, 1397/04/30

Actual recruitment start date

2018-04-07, 1397/01/18

Actual recruitment end date

2018-09-10, 1397/06/19

Trial completion date

2018-09-10, 1397/06/19

Scientific title

The effects of treating myofascial trigger points of neck using the techniques of dry needling and soft tissue release on the clinical feature of patients with migraine headache

Public title

Effects of dry needling and soft tissue release in treatment of migraine patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. A neurologist selected the study subjects based on IHS criteria for diagnosis of migraine. 2. The patients in this study were between the ages of 25 and 55 years old The patients with migraine were examined to find any active trigger points in UT, SCM, sub-occipital muscles . The presence of active trigger points was confirmed if “1- There was an area of focal muscle tenderness that was activated by palpation and that, when activated, referred pain replicating the patient’s headache complaint. 2- There was a jump sign that was the characteristic behavioral response to pressure on a trigger point” . One diagnostic test in particular, the flexion–rotation test, is said to determine C1-2 dysfunction .Patient was supine position. With the subject relaxed and the cervical spine is fully flexed with the occiput resting against the examiners. The head is then rotated to the left and the right. If firm resistance is percieved, pain provoked and range is limited before the expected end range .The normal range is reported at 44-45 degrees, therefore, the test is positive when the range of motion is more than 10 degrees from the normal range.Studies have shown that migraine has a small effect on the range of motion during this test, but this test shows the presence or absence of cervicogenic headache and this test can use for Differential Diagnosis between migraine headache and cervicogenic headache.The positive test indicates a cervicogenic headache

Exclusion criteria:

history of cervical disc herniation, unusual migraine, heart failure, pulmonary failure, kidney failure, liver failure, circulation failure, diabetes mellitus patients who were using opioid prophylaxis, anti -depressant, anti-anxiety drugs subjects who were pregnant or breastfeeding and Those who having trigger point therapy within the past month before the study The patients, who underwent DN, had no contraindication for needling such as local infection, pregnancy with threatened abortion, taking anticoagulants

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **20**
20 subjects per group
Actual sample size reached: **68**
More than 1 sample in each individual
Actual sample size in each individual: **20**
20 subjects per group

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Double-blind study will be done,in this way, the allocation of people to the groups and the assessment of patients are done by people who are unaware of the status of the grouping of patients.Treatment is provided by a specialist physiotherapist and evaluated by a collaborator.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the University of Social Welfare and Rehabilitation Sciences

Street address

Koodakyar St., Daneshjoo Blvd,Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985713834

Approval date

2016-06-19, 1395/03/30

Ethics committee reference number

IR.USWR.REC.1395.192

Health conditions studied

1

Description of health condition studied
Migraine patients
ICD-10 code
I67.8
ICD-10 code description
Other specified cerebrovascular diseases

Primary outcomes

1

Description
1-Headache frequency
Timepoint
Before,After and 1month follow up
Method of measurement
Daily note form

2

Description
2-Headache intensity
Timepoint
Before,After and 1month follow up
Method of measurement
Daily note form

3

Description
3-Headache duration
Timepoint
Before,After and 1month follow up
Method of measurement
Daily note form

4

Description
Number of drug consumption
Timepoint
Before,After and 1month follow up
Method of measurement
Daily note form

Secondary outcomes

1

Description
1.Pressure pain threshold
Timepoint
Before, After and 1month follow up
Method of measurement
Algometer

2

Description
2-Muscle thickness
Timepoint
Before, After and 1month follow up
Method of measurement
Ultrasonography

3

Description
3-Range of motion
Timepoint
Before, After and 1month follow up
Method of measurement
Goniometer

4

Description
4-Neck disability index
Timepoint
Before, After and 1month follow up
Method of measurement
Neck disability index questionnaire

5

Description
5-Head disability index
Timepoint
Before, After and 1month follow up
Method of measurement
Head disability index questionnaire

6

Description
6-Pain intensity
Timepoint
Before, After and 1month follow up
Method of measurement
Visual analog scale

Intervention groups

1

Description
Intervention group: Dry needling
Category
Rehabilitation

2

Description
Intervention group: Soft tissue release
Category
Rehabilitation

3

Description
Control group: Placebo control
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Visual analog scale, Algometer, Ultrasonography, Goniometer,Neck disability index questionnaire and
Full name of responsible person
Dr.Mansour Hedayati
Street address
Shiraz Shahid Chamran Avenue - Student Square - next to Amin Ali Pharmacy - Eram Building - Third Floor
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences
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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
Some of the data, such as information about the consequences, can be shared

When the data will become available and for how long
Starting the access period: 6 months after publition the results

To whom data/document is available
Researchers working in academic and academic institutions

Under which criteria data/document could be used
Only statistical analyzes can be used to find treatment for improvement of patients

From where data/document is obtainable
Applicants can be guided by email authors

What processes are involved for a request to access data/document
First, they will email the authors of the study and we Will be answered within a week

Comments