

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effects of upper trapezius active trigger points dry needling on postural control and clinical signs in women with chronic non-specific neck pain (a single blind randomized clinical trial)

#### Protocol summary

##### Study aim

examining effects of upper trapezius active trigger points dry needling on postural control and clinical signs in women with chronic non-specific neck pain

##### Design

A blocking randomized, blinded, controlled clinical trial with a parallel group design of 30 patients.

##### Settings and conduct

The study is performed in rehabilitation faculty of Iran university of medical sciences. Eligible participants sign consent form and are randomly assigned in intervention or control group by blocking. Pain, pain pressure threshold, cervical side bending and rotation range of motion to both sides, center of pressure displacement and functional disability are assessed at first session before, 2 days and 2 months after intervention. Treatment and assessment is done by separate persons and assessor is blind about participants' groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range from 18-35 years, history of neck pain in the last 3 months, presence of at least 3 and not more than 6 neck pain based on visual analogue scale, presence of at last 3 active trigger points in upper Trapezius muscle. Exclusion criteria: History of surgery or trauma in cervical spine or upper limb , neurological disorders, vestibular disorders, acute cognitive disorders, acute psychopathy

##### Intervention groups

In intervention group, participants receive dry needling with upper trapezius passive stretch and postural correction education. In control group, stretch and education will be done.

##### Main outcome variables

pain; pain pressure threshold; side bending & rotation range of motion; postural control; functional rating scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191208045652N1**

Registration date: **2020-03-03, 1398/12/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-03-03, 1398/12/13**

Update count: **0**

##### Registration date

2020-03-03, 1398/12/13

##### Registrant information

##### Name

marzieh Yassin

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 8052

##### Email address

m.yassin.pt@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-22, 1398/09/01

##### Expected recruitment end date

2020-05-19, 1399/02/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effects of upper trapezius active trigger points dry needling on postural control and clinical signs in women with chronic non-specific neck pain (a single blind randomized clinical trial)

## Public title

Effects of upper trapezius active trigger points dry needling in women with chronic non-specific neck pain

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age range from 18-35 years History of neck pain in the last 3 months Presence of neck pain at least 3 and not more than 6 based on visual analogue scale during last week Presence of at least 3 active trigger points in upper Trapezius muscle, based on Simons et al criteria: 1) presence of palpable taut band 2) presence of hyperirritable spots in a taut band based on participants' history 3) presence of referral pain in a specific pattern during compression or stretch 4) Patient's recognition of current pain complaint by pressure on the tender nodule 5) jump sign during palpation of spot

### Exclusion criteria:

History of cervical spine or upper limb surgery during the last year History of traumatic injuries in cervical region including fracture, whiplash during the last year Presence of radiculopathic signs Presence of pain in hip, knee & ankle during the last 3 months Presence of neurological disorders including Neuropathy, Myopathy, Parkinson & Cerebellar lesion Presence of vestibular disorders Presence of uncorrected visual & hearing disorders Presence of acute cognitive disorders ( result number < 23 from MMSE questionnaire) Presence of acute psychopathy (based on acquired number from DASS-21 questionnaire) History of rheumatic disorders History of fibromyalgia syndrome based on Rheumatology faculty of USA (1990) History of coagulopathy Pregnancy Diabetes History of any treatment or injection of trigger points during the last 3 months Visible severe postural disorders including kyphosis or scoliosis Skin infection or inflammation History of anti coagulant or immunosuppressive drugs Fear of needle

## Age

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

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this study, a simple block random allocation method will be used. In order to balance the number of samples

in each group, a blocking method with random sizes of 6 will be used and non-transparent envelopes will be used to hide the random assignment. It should be noted that steps are taken to create a randomization sequence by a person who is not involved in any other stage of the research

## Blinding (investigator's opinion)

Single blinded

## Blinding description

treatment and assessment will be done by separate persons. Analyzer and assessor will be blind.

## 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

۱۴۳۹۶۱۴۵۳۵

#### Approval date

2019-11-05, 1398/08/14

#### Ethics committee reference number

IR.IUMS.REC.1398.848

## Health conditions studied

### 1

#### Description of health condition studied

nonspecific neck pain

#### ICD-10 code

M70.9

#### ICD-10 code description

Unspecified soft tissue disorder related to use, overuse and pressure

## Primary outcomes

### 1

#### Description

postural control

#### Timepoint

Before intervention, 2 days and 2 months after intervention

**Method of measurement**

Force plate, kistler, Germany

**Secondary outcomes**

**1**

**Description**

Pain

**Timepoint**

Before intervention, 2 days and 2 months after intervention

**Method of measurement**

visual analogue scale

**2**

**Description**

pain pressure threshold

**Timepoint**

Before intervention, 2 days and 2 months after intervention

**Method of measurement**

Algometer, JTECK, USA

**3**

**Description**

side bending & rotation range of motion

**Timepoint**

Before intervention, 2 days and 2 months after intervention

**Method of measurement**

iPhone 8 application, goniometer

**4**

**Description**

functional rating scale

**Timepoint**

Before intervention, 2 days and 2 months after intervention

**Method of measurement**

Persian version of functional rating scale questionnaire

**Intervention groups**

**1**

**Description**

Intervention group:dry needling (Dang bang South Korea, 50\*0.3 millimeter) with upper trapezius passive stretch and postural correction education based on pamphlet during 5 sessions, 2 times in a week.

**Category**

Rehabilitation

**2**

**Description**

Control group: upper trapezius passive stretch and postural correction education based on pamphlet during 5 sessions, 2 times in a week.

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

physiotherapy clinic of rehabilitation faculty of Iran university of medical sciences

**Full name of responsible person**

Marzieh Yassin

**Street address**

Faculty of rehabilitation of Iran university of medical sciences, Madadkaran St, Shah nazari St, Madar Sq, Mirdamad Blv.

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rehab@iums.ac.ir

**2**

**Recruitment center**

**Name of recruitment center**

Golestan dormitory of Iran university of medical sciences

**Full name of responsible person**

Marzieh Yasin

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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 Motevalian

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Iran university of medical sciences, Milad tower,  
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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**

Fereshteh Navaee

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for scientific

## inquiries

**Contact**

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Marzieh Yassin

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for updating data

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Iran University of Medical Sciences

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**Position**

assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Not applicable

**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

**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**

Use 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**

connect to Fereshteh Navaee by email:  
fereshte.navaei@gmail.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 as soon as possible.

**Comments**