

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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, wiplash 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 immuno suppressive 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

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Tehran

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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

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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

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Person responsible for scientific

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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

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