

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Sep 2026

study of the effects of a single session dry needling with and without intramuscular electrical stimulation on active trigger point in patients with shoulder impingement syndrome

Protocol summary

Study aim

the effectiveness of Dry Needling with and without intramuscular electrical stimulation on pain and function in patients with impingement syndrome

Design

clinical randomised trial, parallel group with assessor blind

Settings and conduct

in this study patients with shoulder impingement syndrome who are referred to the clinic of Shahid Beheshti University, are included and divided randomly to two groups. patients are assessed by a assessor who is blind to the intervention and then they undergo dry needling for trigger points on Upper Trapezius and Infra Spinatus muscle.

Participants/Inclusion and exclusion criteria

inclusion: patients diagnosed with impingement syndrome who have active trigger point in upper trapezius and infra spinatus muscle, age between 18-20, moderate intensity of pain based on VAS
exclusion: having any musculoskeletal disorder or neurological disorder in neck or upper limb, patients who are afraid of needle, pregnancy

Intervention groups

intervention group 1 includes impingement syndrome patients receiving 1 minute of fast in-fast out dry needling on trigger point in upper trapezius and infraspinatus muscle. then the needle is remained in the trigger point for 10 minutes intervention group 2 includes impingement syndrome patients receiving dry needling with intramuscular electrical stimulation. dry needling is done like the other group for 1 minute. then the cathode electrode is attached to the needle with alligator clips and the anode electrode is placed on spinous process of C7. the electrical stimulation type is burst and will be set with a frequency of 2Hz and pulse duration 200µs and the intensity increase to elicit muscular contraction

without pain. the stimulation is applied on each needle separately for 10 minutes.

Main outcome variables

it is expected that this technique will be effective on pain, pain pressure threshold, range of motion and shoulder function.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180410039256N1**

Registration date: **2018-12-09, 1397/09/18**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-09, 1397/09/18**

Update count: **0**

Registration date

2018-12-09, 1397/09/18

Registrant information

Name

Sayena Vahidimanesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7756 1724

Email address

vahidimanesh1372@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-22, 1397/07/30

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
study of the effects of a single session dry needling with and without intramuscular electrical stimulation on active trigger point in patients with shoulder impingement syndrome

Public title
study of the effects of dry needling with and without intramuscular electrical stimulation on shoulder pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 patients with shoulder impingement syndrome who have 3 positive tests among neer, hawkins kennedy, jobe, external rotation resistance, painful arc age between 18 to 50 presence of active trigger points in upper trapezius and infraspinatus muscles moderate pain intensity of 3 based on VAS
Exclusion criteria:
 any postural disorders like scoliosis ect frozen shoulder any other musculoskeletal disease like myopathy, neck and shoulder surgery etc neurological disease malignancy absolute and relative contraindication use of dry needling for women being on period time

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
patients will be randomly divided to one of the two intervention groups. 15 cards are considered for each group. these cards are placed in sealed envelopes and each patients will get one.

Blinding (investigator's opinion)
Single blinded

Blinding description
in this study the assessor is blind to the treatment the data analyser will be blind too

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Shahid Beheshti University of Medical Sciences

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

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Postal code

19839-63113

Approval date

2018-03-17, 1396/12/26

Ethics committee reference number

IR.SBMU.RETECH.REC.1396.1397

Health conditions studied

1

Description of health condition studied

shoulder impingement syndrome

ICD-10 code

M75.4

ICD-10 code description

Impingement syndrome of shoulder

Primary outcomes

1

Description

intensity of pain

Timepoint

before the intervention, immediately after the intervention, one week after treatment

Method of measurement

Visual Analogue Scale

2

Description

active shoulder range of motion

Timepoint

before the intervention, immediately after the intervention, one week after treatment

Method of measurement

Goniometry

3

Description

pain pressure threshold

Timepoint

before the intervention, immediately after the intervention, one week after treatment

Method of measurement

digital Algometer

Secondary outcomes

1

Description

disability of the arm, shoulder and hand

Timepoint

before the treatment, one week after treatment

Method of measurement

persian version of Disability of the Arm, Shoulder, Hand

Intervention groups

1

Description

Intervention group: dry needling

Category

Treatment - Other

2

Description

Intervention group: dry needling with intramuscular electrical stimulation

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti school of rehabilitation Sciences

Full name of responsible person

mohammad mohsen roostaei

Street address

SBMU School of Rehabilitation Sciences, Damavand St, Across from Bu Ali Hospital, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Bldg No.2, Shahid Arabi Ave, yaman St, Chamran Hwy

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zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sayena Vahidimanesh

Position

master student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

mohammad mohsen roostaei

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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Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

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