

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Comparison of the effect of the two different methods of dry needling in patients with shoulder impingement syndrome

Protocol summary

Shoulder Pain and Disability, pain Intensity, pressure pain threshold

Study aim

Comparison of the effect of two different methods of dry needling in patient with shoulder impingement syndrome

Design

A randomized controlled trial, 2 parallel groups with a control group, single-blinded, design of 48 cases

Settings and conduct

Field of Study: The effect of different dry needles methods in patients with impingement syndrome.
location: Faculty of Rehabilitation, Shiraz University of Medical sciences. method: Patients will be treated With routine physical therapy treatment. Finally, a statistical comparison of different needling methods in the 1st & 2nd groups will be performed. The data collector researcher will be unaware of the patient's classification.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged between 20 and 55, positive Hawkins-Kennedy and Neer's sig tests, existence of at least one trigger point in the infraspinatus muscle, matching the pattern of trigger points with patient pain,
Exclusion criteria: History of shoulder injections, history of shoulder surgery, glenohumeral instability, history of physiotherapy in the past 3 months, signs of systemic disorders, use of corticosteroids drugs in the last 3 months, overhead sport & activity, and any restrictions on dry needling,

Intervention groups

1st intervention group (10 consecutive sessions of physiotherapy including interferential therapy, Hot packs and exercise therapy plus three sessions of dry needle infra-spinatus trigger points by deep methods) 2nd intervention group (10 consecutive sessions of physiotherapy including interferential therapy, Hot packs and exercise therapy plus three sessions of dry needle infra-spinatus trigger points by Hong methods)
3. Control group (10 consecutive sessions of physiotherapy including interferential therapy, Hot packs and exercise therapy)

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190409043210N1**

Registration date: **2020-01-11, 1398/10/21**

Registration timing: **prospective**

Last update: **2020-01-11, 1398/10/21**

Update count: **0**

Registration date

2020-01-11, 1398/10/21

Registrant information

Name

Mehrdad Emani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-04, 1398/11/15

Expected recruitment end date

2020-04-03, 1399/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of the two different methods of dry needling in patients with shoulder impingement syndrome

Public title

Dry needling of shoulder pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Impingement syndrome cases with positive Hawkins-kennedy and Neer's sig presence of at least one active or inactive trigger point in the infraspinatus muscle matching Pattern of trigger points with patient pain based on references age between 20-55

Exclusion criteria:

Shoulder injection history shoulder surgery history glenohumeral instability Shoulder physiotherapy in the last 3 months Symptoms indicate systemic disorders Taking corticosteroid anti-inflammatory drugs over the past 3 months history of sport & over head activity Patients with any restrictions on dry needling

Age

From **20 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

The way to assigning people to 3 groups based on the Permuted block randomization (6 people in every block) is according to Random Allocation software.

Blinding (investigator's opinion)

Single blinded

Blinding description

All stages of measurement and treatment will be performed by two researchers. The process of classification and treatment of patients will be performed by the first researcher. The second researcher will not be informed about the classification and interventions of patients and Will only collaborate on patient evaluation. Therefore, the blindness of the assessor will be performed.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Central building of Shiraz University of Medical Sciences, Zand Street

City

Shiraz

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۷۱۳۳۶ - ۷۱۳۴۸

Approval date

2019-03-18, 1397/12/27

Ethics committee reference number

IR.SUMS.REHAB.REC.1397.024

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**

Pain intensity

Timepoint

Before the intervention, at the end of tenth session, and four weeks after the last session of treatment

Method of measurement

Numeric pain rating scale

2**Description**

Shoulder pain and disability

Timepoint

Before the intervention, at the end of tenth session, and four weeks after the last session of treatment

Method of measurement

Shoulder Pain and Disability Index

3**Description**

Pressure pain threshold

Timepoint

Before the intervention, at the end of tenth session, and four weeks after the last session of treatment

Method of measurement

Digital pain pressure algometer (Wagner RS232)

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Ten consecutive sessions of routine physical therapy for shoulder, including exercise and interferential therapy with hot pack and three sessions of deep dry needling for Infraspinatus muscle in the third, fifth and seventh session of the main therapy course.

Category

Rehabilitation

2

Description

second intervention group: Ten consecutive sessions of routine physical therapy for shoulder, including exercise and interferential therapy with hot pack and three sessions of dry needling by Hong method for Infraspinatus muscle in the third, fifth and seventh session of the main therapy course.

Category

Rehabilitation

3

Description

Control group: Ten consecutive sessions of routine physical therapy for shoulder, including exercise and interferential therapy with hot pack.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy Clinic of shiraz rehabilitation Faculty

Full name of responsible person

Shohreh Taghizadeh

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Sponsors / Funding sources

1

Sponsor

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mehrdad Emani

Position

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