

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of dry needling on subscapularis and conventional physiotherapy on clinical symptom improvement in people with frozen shoulder

Protocol summary

Study aim

the aim of this study is to investigate the effect of dry needling on the trigger points of the subscapularis muscle and to improve the clinical symptoms of people with frozen shoulder.

Design

Randomized clinical trial with the control group, with parallel groups, single-blinded, on 40 patients, randomization allocation software will be used for randomization.

Settings and conduct

Patients randomly will be divided into two groups. The first group (intervention group) will receive dry needling of the subscapularis muscle during 3 sessions. At the same time, They also benefit from conventional physiotherapy treatment, but the control group will only use conventional physiotherapy treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: subjects were diagnosed with frozen shoulder . the presence of active trigger points in the subscapularis muscle Exclusion criteria: needle phobia

Intervention groups

The intervention group consists of patients with frozen shoulder. Routine physiotherapy includes Continuous ultrasound with a frequency of 3 MHz for 6 minutes, high-intensity electric current with a frequency of 100 Hz and diversion of 20 minutes, hot pack simultaneously with the application of the current. Postero-anterior, Antero-posterior and caudal glides. The shoulder muscles stretching and active-assistive exercises using a towel as well. They also will receive 3 sessions of dry needling. The control group consists of patients with frozen shoulder who will only receive routine physiotherapy.

Main outcome variables

Shoulder range of motion; intensity of pain in trigger points of the subscapularis muscles and shoulder joint; Pain pressure threshold of trigger points; Upper limb functional disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200215046499N3**

Registration date: **2023-04-25, 1402/02/05**

Registration timing: **prospective**

Last update: **2023-04-25, 1402/02/05**

Update count: **0**

Registration date

2023-04-25, 1402/02/05

Registrant information

Name

Hakimeh Adigozali

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3337 5359

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-20, 1402/03/30

Expected recruitment end date

2024-03-10, 1402/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of dry needling on subscapularis and conventional physiotherapy on clinical symptom improvement in people with frozen shoulder

Public title

Effects of dry needling and physiotherapy in patients with frozen shoulder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Those who have been diagnosed with frozen shoulder by a doctor and have symptoms such as pain and reduced range of motion in the capsular pattern in the shoulder joint for 3 months or more age between 35 and 65 years old the presence of active trigger points in the subscapularis muscle on the involved side Pain intensity of at least 3 out of 10 in the VAS

Exclusion criteria:

skin problems in the neck and shoulder area Antiplatelet therapy has been used in the three days before the start of the study In the six months before starting the study, they had a history of cancer and related pain in the shoulder and pectoral region In the three months before the start of the study, they used corticosteroid injections in the shoulder area needle phobia Non-cooperation during treatment Shoulder arthroscopy surgery cervical radiculopathy or any neurological injury in upper limb Patients with rheumatoid or neurological diseases Patients who use pace makers Patients with positive subacromial entrapment tests

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with a sealed envelope: Two envelopes are prepared with the first and second group titles. Each participant randomly selects one envelope and the envelope number is recorded for the participant. The envelopes are then merged and the next participant selects another envelope from the two envelopes as the previous procedure to complete the randomization process in both groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

evaluator is blind to the type of intervention in each group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of medical sciences

Street address

Faculty of Rehabilitation Sciences, Tabriz University of medical sciences, 29 Bahman Blvd, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166414766

Approval date

2023-03-06, 1401/12/15

Ethics committee reference number

IR.TBZMED.REC.1402.013

Health conditions studied

1

Description of health condition studied

frozen shoulder

ICD-10 code

M75.00

ICD-10 code description

Adhesive capsulitis of unspecified shoulder

Primary outcomes

1

Description

Range of motion of shoulder joint

Timepoint

before and after intervention

Method of measurement

goniometer

Secondary outcomes

1

Description

pain intensity of trigger point

Timepoint

before and after intervention

Method of measurement

Visual analog scale

2

Description

pain intensity of shoulder joint

Timepoint

before and after intervention

Method of measurement

visual analog scale (VAS)

3

Description

Pain pressure threshold of trigger points

Timepoint

before and after intervention

Method of measurement

algometer

4

Description

Upper limb functional disability

Timepoint

at first, fifth and tenth of treatment sessions

Method of measurement

disability of arm, shoulder and hand (DASH)

Intervention groups

1

Description

Intervention group: In addition to receiving the subscapularis dry needling during 3 sessions (in the 3rd, 6th, and 9th sessions of treatment) with a sterile dong bang needle with a size of 30*50 mm, the patient receives conventional physiotherapy treatment provided by the physiotherapist. Conventional treatment includes the use of continuous ultrasound with a frequency of 3 MHz for 6 minutes around the joint capsule, the use of high intensity electric current with a frequency of 80 Hz and diversion for 20 minutes, and the use of a hot pack simultaneously with the application of the current. For the involved shoulder, postero-anterior, antero-posterior and caudal glides can be used with a speed of 2 to 3 glides per second and for a total of 30 seconds for each set. The number of sets for each movement is 5 and the rest time between sets is 30 seconds. We ask the patient to stretch the shoulder muscles as well. The duration of each stretch is 30 seconds and the interval between them is 15 seconds and it is done during 3 sets. We ask the patient to do active-assistive exercises using a towel for 5 minutes a day. The number of conventional treatment sessions is 10 sessions, every other day.

Category

Rehabilitation

2

Description

Control group: People in this group only will receive conventional physiotherapy treatment provided by a physiotherapist. Conventional treatment includes the use

of continuous ultrasound with a frequency of 3 MHz for 6 minutes around the joint capsule, the use of high intensity electric current with a frequency of 80 Hz and diversion for 20 minutes, and the use of a hot pack simultaneously with the application of the current. For the involved shoulder, postero-anterior, antero-posterior and caudal glides can be used with speed of 2 to 3 glides per second and for a total of 30 seconds for each set. The number of sets for each movement is 5 and the rest time between sets is 30 seconds. We ask the patient to stretch the shoulder muscles as well. The duration of each stretch is 30 seconds and the interval between them is 15 seconds and it is done during 3 sets. We ask the patient to do active-assistive exercises using a towel for 5 minutes a day. The number of conventional treatment sessions is 10 sessions, every other day.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

physiotherapy clinic of Asadabadi hospital

Full name of responsible person

Hakimeh adigozalih

Street address

Asad-Abadi hospital, Bahar avenue, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

parviz shahabi

Street address

central building, tabriz university of medical sciences, university street, tabriz

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Grant name

Grant code / Reference number

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

No

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Hakimeh adigozali

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Hakimeh adigozali

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Person responsible for updating data

Contact

Name of organization / entity

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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