

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The Comparative Effect of Phonophoresis and Injection of Triamcinolone with lidocain on Pain, Disability, Quality of Life and Effectiveness of Treatments in Shoulder Impingement Patients

Protocol summary

Study aim

The purpose of this study was to compare the effect of two methods of injection and phonophoresis of triamcinolone 1% with lidocaine on pain and disability in patients with shoulder impingement syndrome.

Design

Patients are transmitted into two groups based on simple randomization with closed envelopes in which numbers 1-44 are transmitted so that the even numbers enter into the injection group and the odd numbers into the phonophoresis group. Based on the mean and standard deviation of the SPADI questionnaire score in similar articles, 22 individuals in each group, with a 10% drop is considered.

Settings and conduct

Physical Therapy clinic of Qaem Hospital

Participants/Inclusion and exclusion criteria

Individuals with shoulder impingement syndrome included by orthopedic physician. Patients are divided randomly into two groups of injections and phonophoresis after being evaluated based on inclusion and exclusion criteria .

Intervention groups

In the first group, phonophoresis treatment will be performed in 5 sessions, 3 times a week. The phonophoresis group received 10 minutes of phonophoresis (1% triamcinolone with lidocaine) in the supraspinatus and biceps tendons while the patient is half asleep at a 60° angle and shoulder in the extension and internal rotation position with the frequency of ultrasound 3MHz and the intensity of 1.5 W / Cm2 . After performing the phonophoresis, the patient will be asked to remove gauze after 2 hours and remove the cream. The amount of triamcinolone that each patient uses is equivalent to 16 mg, receiving a total 80 mg during 5 treatment sessions. The second group, after evaluating the outcomes, will be given by the orthopedic surgeon to

administer the triamcinolone with lidocaine in the subacromal region.

Main outcome variables

VAS SPADI questionnaire WORC questionnaire GRC

General information

Reason for update

Decrease sample size

Acronym

IRCT registration information

IRCT registration number: **IRCT20161221031506N3**

Registration date: **2019-02-27, 1397/12/08**

Registration timing: **prospective**

Last update: **2021-12-13, 1400/09/22**

Update count: **1**

Registration date

2019-02-27, 1397/12/08

Registrant information

Name

Salman Nazary-Moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3884 6713

Email address

nazaryms@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-06, 1397/09/15

Expected recruitment end date

2019-05-19, 1398/02/29

Actual recruitment start date

2019-05-24, 1398/03/03

Actual recruitment end date

2019-09-16, 1398/06/25

Trial completion date

2019-09-16, 1398/06/25

Scientific title

The Comparative Effect of Phonophoresis and Injection of Triamcinolone with lidocain on Pain, Disability, Quality of Life and Effectiveness of Treatments in Shoulder Impingement Patients

Public title

The Comparison of two approach of drug transition in shoulder impingement patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Pain less than 3 month Pain in the upper, outer arm especially when lifting of arm Aged 18-65 years Signs of shoulder impingement syndrome : Presence of at least two of the following 1) Painful arch movement during flexion or abduction of the shoulder 2) Positive Neer or Hawkins-Kennedy test 3) Painful resisted external rotation, abduction or painful jobe (empty can) test

Exclusion criteria:

Existence of type 3 acromion Existence of frozen shoulder (the loss in passive shoulder range of motion greater than 50% as compared to the uninvolved side in at least 2 shoulder movements) Existence of neck radiculopathy Existence of Complete rupture of rotator cuff muscles (MRI findings) Existence of shoulder joint instability (Positive tests of sulcus or apprehension) Use of corticosteroid drugs in last 3 months History of RSD History of any neurological diseases History of rheumatoid diseases and shoulder osteoarthritis History of fracture or dislocation or surgery in the shoulder complex

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **24**Actual sample size reached: **24****Randomization (investigator's opinion)**

Randomized

Randomization description

Participants choose to pick one of the sealed envelopes. Another physiotherapist who does not know how to group and do the study will evaluate the patients.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

The Ethics Committee of Mashhad University of Medical Sciences

Street address

Opposite University Street 18, University street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2019-01-09, 1397/10/19

Ethics committee reference number

IR.MUMS.REC.1397.251

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

Timepoint

visit time- after 10 days placebo intervention- after 10 days treatment period

Method of measurement

visual analog scale

2**Description**

Disability

Timepoint

visit time- after 10 days placebo intervention- after 10 days treatment period

Method of measurement

by SPADI questionnaire

3

Description

quality of life

Timepoint

visit time- after 10 days placebo intervention- after 10 days treatment period

Method of measurement

by WORC questionnaire

4

Description

treatment effect

Timepoint

discharge time

Method of measurement

by Global Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group#1 (Injection): The triamcinolone (Cortiran, Iran hormone, Tehran, Iran) and lidocaine (Caspian, Iran tamin, Tehran, Iran) will be injected by the orthopedic physician in subacromial space. Then, the patients were requested to return to orthopedic ward for completing all questionnaires again. The drug dosage that were used for injection include two milliliter triamcinolone ampule and 0.5 cc lidocaine 2%, and 1 cc distilled water.

Category

Treatment - Drugs

2

Description

Intervention group#2 (phonophoresis): The phonophoresis treatment will be done in 5 sessions with one day interval. In these patients, the phonophoresis of triamcinolone 1% (Cortiran, Iran hormone, Tehran, Iran) plus lidocaine (Caspian, Iran tamin, Tehran, Iran) will be done in semi-recumbent position (60 degrees) when the arm place in extenstion and medial rotation. The ultrasound current will be pulse, frequency 3 MHz , and intensity 1.5 Wcm-2. The assessment will be done after five sessions. The topical cream ,produced by Pharmaceutics department of the pharmacy school of the Mashhad University of Medical Sciences, Mashhad, Iran, that were used for phonophoresis include 80 milligram triamcinolone and 0.5 cc lidocaine 2%.

Category

Treatment - Drugs

3

Description

Control group: placebo tablets. Before and after 10 days placebo treatment (#placebo) will be performed by the prescription of placebo tablet (vitamin C) and giving educational pamphlet.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical Therapy Clinic of Ghaem Hospital

Full name of responsible person

Mr Javad Zarandi

Street address

Nursing door entrance, right side, library side, Narjes building, first floor, Physiotherapy Department, Ghaem Hospital,

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3841 1538

Email

zarandiMJ1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Doctora Cross road, Ghoreshi Building

City

Mashhad

Province

Razavi Khorasan

Postal code

9919191778

Phone

+98 51 3841 1538

Email

vcresearch@mums.ac.ir

Grant name

ersonal Grant (Dr Salman Nazary-Moghadam)

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Mohammadreza Mazaheri Tehrani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street addressMashhad- Azadi Square- East door of Ferdowsi
University of Mashhad- University campus- Faculty of
Paramedical Sciences**City**

Mashhad

Province

Razavi Khorasan

Postal code

9177948964

Phone

+98 51 3869 8719

Email

mtmazaheri@outlook.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mohammadreza Mazaheri Tehrani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Province

Razavi Khorasan

Postal code

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Phone

+98 51 3869 8719

Email

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Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

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Student

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Postal code

9177948964

Phone

+98 51 3869 8719

Email

Mtmazaheri@outlook.com

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**

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic CodeUndecided - 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 reports will be reported in one research paper. Raw
data will be delivered to researchers for meta analysis.**When the data will become available and for how long**

Starting 6 months after publication

To whom data/document is available

For researchers

Under which criteria data/document could be used

فقط برای متاآنالیز

From where data/document is obtainable

Nazary_salman@yahoo.com

What processes are involved for a request to access data/document

The response will be sent 3 months after considering the researcher's request.

Comments