Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Age
From **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 address
Mashhad- 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
Mohamadreza Mazaheri Tehrani
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
Mashhad- 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 updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohamadreza Mazaheri Tehrani
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
Mashhad- 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

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 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 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