

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the effectiveness of ultrasound guided prolotherapy in supraspinatus tendon with ultrasound guided corticosteroid injection of subacromial subdeltoid bursa in rotator cuff related shoulder pain

Protocol summary

Study aim

Comparison of the effectiveness of ultrasound guided prolotherapy in supraspinatus tendon with ultrasound guided corticosteroid injection of subacromial subdeltoid bursa in rotator cuff related shoulder pain in patients referring to physical medicine and rehabilitation clinics in Shiraz during 2018-2019

Design

A randomized clinical trial including 2 comparing groups of steroid injection and dextrose50% injection with double blinded method

Settings and conduct

This research is a clinical trial study using the formula for comparing the mean in the community with alpha 5% and the power of 80% , the minimum sample size is 24 patients which is assessed with a drop of 5% in each group of 25 patients . we will include 30-65 year old patients with definitive clinical diagnosis of rotator cuff lesions (history and physical exam) referring to PM and R units under supervision of shiraz university of medical sciences in shiraz during 1397-1398 and the patients will be randomly allocated in two groups by block randomization assignment and double blind methods

Participants/Inclusion and exclusion criteria

30- 65 year old patients with long standing symptoms of at least 6 months or refractory to conservative managements for 3 months with rotator cuff lesion diagnosed in forms of tendinitis or partial tear by sonography or MRI are included and patients with RA, DM, osteomyelitis, active infectious disease, chronic infection in site of injection ,bleeding tendency, pregnancy previous operation of site of injection and previous local injection in treatment site in 12 weeks ago are excluded

Intervention groups

2 groups for ultrasound guided injection are randomly allocated that in one group injection of steroid in bursa

and in other group injection of dextrose50% in supraspinatus tendon are done

Main outcome variables

Pain and disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191129045542N1**

Registration date: **2020-05-08, 1399/02/19**

Registration timing: **retrospective**

Last update: **2020-05-08, 1399/02/19**

Update count: **0**

Registration date

2020-05-08, 1399/02/19

Registrant information

Name

Leilasadat Mohamadijahromi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3648 6034

Email address

mohamadil.2668@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-11, 1398/09/20

Expected recruitment end date

2020-02-09, 1398/11/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of ultrasound guided prolotherapy in supraspinatus tendon with ultrasound guided corticosteroid injection of subacromial subdeltoid bursa in rotator cuff related shoulder pain

Public title
Comparison of the effectiveness of ultrasound guided prolotherapy in supraspinatus tendon with ultrasound guided corticosteroid injection of subacromial subdeltoid bursa in rotator cuff related shoulder pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
patients from 30-65 year old with long standing symptoms of at list 6 months or refractory to at list 3 months of conservative methods rotator cuff lesions in the forms of tendinitis, partial tear which are diagnosed by sonography or MRI
Exclusion criteria:
Patients with RA, DIABETES, OSTEOMYELITIS, Active infectious disease, history of chronic infection in the treatment area, positive history of previous operation of the involved shoulder positive history of local injection at treatment area in 12 weeks ago bleeding tendency pregnancy frozen shoulder

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly allocated in to 2 groups by block randomization assignment and double blind methods. Based on sequences designed according to the block randomization method, for each patient the injectable material will be prepared in another room by non injectable person who is oriented. Then the syringe containig the injectable drug is brought to the injector in the sonography room

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients will be randomly allocated in to 2 groups by block randomization assignment and double blind

methods. Based on sequences designed according to the block randomization method, for each patient the injectable material will be prepared in another room by non injectable person who is oriented. Then the syringe containig the injectable drug is brought to the injector in the sonography room

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of Shiraz University of Medical Sciences

Street address

Unit 4 in Shahab building, Koohbor4 line, Namazi street, Satarkhan street, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7184747538

Approval date

2018-08-15, 1397/05/24

Ethics committee reference number

IR.SUMS.MED.REC.1397.186

Health conditions studied

1

Description of health condition studied

rotator cuff dysfunction

ICD-10 code

M75.100

ICD-10 code description

Unspecified rotator cuff tear or rupture of unspecified shoulder, not specified as traumatic

Primary outcomes

1

Description

pain and disability of shoulder

Timepoint

before, 3 and 12 weeks after injection

Method of measurement

visual analogue scale and shoulder pain and disability scale

Secondary outcomes

1

Description

scores of function and quality of life

Timepoint

before, 3 and 12 weeks after injection

Method of measurement

shoulder pain and disability index

Intervention groups

1

Description

Intervention group1: patients with chronic supraspinatus tendinopathy who recieved prolotherapy in multiple points of injured tendon

Category

Treatment - Other

2

Description

Intervention group2: patients with chronic supraspinatus tendinopathy who recieved corticosteroid injection in subacromial bursa

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical medicine and rehabilitation unit in Imam Reza clinic

Full name of responsible person

Aref Nasiri

Street address

Namazi square

City

Shiraz

Province

Fars

Postal code

-

Phone

+98 71 3212 7002

Email

nasiri.aref@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Aref Nasiri

Street address

Zand avenue

City

Shiraz

Province

Fars

Postal code

-

Phone

+98 71 3212 7002

Email

nasiri.aref@yahoo.com

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

Aref Nasiri

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Zand avenue, Faghihi hospital

City

Shiraz

Province

Fars

Postal code

-

Phone

0098712319040

Email

nasiri.aref@yahoo.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Aref Nasiri

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Zand avenue, Faghihi hospital

City

Shiraz

Province

Fars

Postal code

-

Phone

00982319040

Email

nasiri.aref@yahoo.com

Postal code

-

Phone

0098712319040

Email

nasiri.aref@yahoo.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

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

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

--

From where data/document is obtainable

-

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

-

Comments

-

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Aref Nasiri

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Zand ave, Faghihi hospital

City

Shiraz

Province

Fars