

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Evaluation of the efficacy of three different methods in the treatment of rotator cuff tendinopathy of shoulder; Dextrose-prolotherapy, Corticosteroid injections and Physical therapy.

Protocol summary

Study aim

Comparative study of the effectiveness of 3 methods of corticosteroid injections, prolotherapy with dextrose and physical exercise in treatment of partial tearing of rotator cuff tendons in the shoulder

Design

In this study, a phase 3 clinical trial, 114 patients aged 65-18 years old with shoulder pain were enrolled in the study according to the inclusion criteria. All patients are trained in the Numerical Rating Scale and SPADI shoulder disability criteria. Each patient will be randomly distributed in one of three groups: Prolotherapy, Corticosteroid and Physical exercises.

Settings and conduct

Patients with shoulder pain referring to the pain clinic of Imam Hossein and Akhtar hospitals will participate in this study.

Participants/Inclusion and exclusion criteria

Patients aged 18 to 65 years with shoulder pain (for at least 6 weeks) who inflammation and relative damage to rotator cuff tendons are approved by physical examination and imaging techniques, are included in the study. Patients with a history of shoulder surgery, diabetes, malignancy, and various types of immune system disorders will not be included in the study.

Intervention groups

Group P (Prolotherapy): 8 cc of dextrose solution of 12.5% contains 40 mg lidocaine in the 3-5 points around the shoulder joint. Group C (corticosteroid): 8 cc of 0.1% lidocaine solution containing 80 mg of triamcinolone will be injected in the area surrounding the supraspinatus and sub-scapular tendons and around the suprascapular nerve. Group E (physical exercises): 8 cc of lidocaine solution 1% in the area around the supraspinatus and sub-scapular tendons and around the suprascapular nerve. Then, after 1 week, 10 sessions of physical therapy will be started with Tense, Ultrasound, Hot

Package modalities.

Main outcome variables

Partial damage of rotator cuff tendons; Pain; Shoulder disability; Prolotherapy; Corticosteroid; Physical treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101113005172N4**

Registration date: **2018-10-24, 1397/08/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-24, 1397/08/02**

Update count: **0**

Registration date

2018-10-24, 1397/08/02

Registrant information

Name

Saman Asadi

Name of organization / entity

Anesthesiology ward of Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1231 8072

Email address

asadisa@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of three different methods in the treatment of rotator cuff tendinopathy of shoulder; Dextrose-prolotherapy, Corticosteroid injections and Physical therapy.

Public title

Comparison of therapeutic effect of prolotherapy by glucose, corticosteroid and physical therapy in shoulder tendinopathy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Shoulder pain for at least 6 weeks Rotator cuff tendinopathy has been confirmed by physical examination and imaging methods Patient between 18-65 years old

Exclusion criteria:

Past history of shoulder surgery Diabete mellitus Malignancy Immune insufficiency disorders

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize the arrival of patients in each of the three study groups, a restricted randomization method using the random allocation rule will be done. This randomization method is used to balance the number of people assigned to each of the groups at the end of the sample collection. In this study, taking into account 38 patients for each group, a total of 120 patients will be considered for entry and randomization. In this method, 120 small balls of the same size are considered in three different colors; 30 yellow balls representing prolotherapy, 30 blue balls representing corticosteroids and 30 green balls representing physical therapy. All small balls are placed in a bag and for each patient, a ball is pulled out of the bag.

Blinding (investigator's opinion)

Double blinded

Blinding description

At the beginning of the study, all patients in the three groups will be injected in the same place. Post-injection care is the same in all three groups. The only difference is in patients with the "physical therapy" group, which physical therapies will start 1 week after the injection. It is worth noting that patients in any of the three groups are not aware of the content of the injections. The collecting person as well as the person analyzing the data are not aware of the patient's treatment method.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Aerabi Ave., Yaman Blvd., Shahid Chamran Blvd.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-10-02, 1397/07/10

Ethics committee reference number

IR.SBMU.REC.1397.028

Health conditions studied**1****Description of health condition studied**

Injury or partial tearing of rotator cuff tendons of the shoulder

ICD-10 code

M67.9

ICD-10 code description

Unspecified disorder of synovium and tendon

Primary outcomes**1****Description**

Pain scale and disability in patients with injury or partial tearing of rotator cuff tendons of the shoulder

Timepoint

Measure the pain and disability of the shoulder joint at the beginning of the study (before the intervention) and one week, one month and three months after the end of the treatment interventions

Method of measurement

"Numerical Rating Scale" and "Shoulder Pain And Disability Index"

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Prolotherapy by dextrose. In this group, after placing the patient in the sitting position, 8 cc of dextrose solution 12.5% containing 40 mg lidocaine will be injected in the 3 to 5 points around the shoulder joint (adjacent to the supraspinatus and subscapularis tendons, and other points with tenderness Around the joint) with a 25 gauge, 3.5 cm needle.

Category

Treatment - Other

2

Description

Intervention group 2: Corticosteroid injection. In this group, after placement of the patient in the sitting position and under ultrasound guide, 8 cc of 0.1% lidocaine solution containing 80 mg of triamcinolone will be injected in the area adjacent to the supraspinatus and subscapularis tendons (Needle gauge 25, cm5) and around the suprascapular nerve (Needle, 9 cm , 23 gauge).

Category

Treatment - Other

3

Description

Intervention group 3: Physical therapy. In this group, after placement of the patient in the sitting position and under ultrasound guide, 8 cc of lidocaine solution 1% will be injected in the area adjacent to the supraspinatus and subscapularis tendons (Needle 25 gauge, 5 cm) and around the suprascapular nerve (spinal needle 23 gauge, 9 cm), and after 1 week, the patient will undergo 10 sessions of physical therapy [every other day] with Tense, Ultrasound and Hot Pack modalities.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein hospital

Full name of responsible person

Saman Asadi

Street address

Shahid Madani Ave., Imam Ali Blvd.

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2

Recruitment center

Name of recruitment center

Akhtar hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sayed Ali Ziaee

Street address

Yaman Ave., Shahid Chamran Blvd

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1134845763

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saman Asadi

Position

Pain flowship

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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

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Subspecialist

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

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Position

Pain Flowship

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The individual data of the participants in the research, after being unidentifiable

When the data will become available and for how long

Start the access period, 6 months after printing the results

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

To be used in medical researches

From where data/document is obtainable

Saman Asadi asadisa60@gmail.com

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

Official application through academic or research centers
Comments