

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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.

#### City

Tehran

#### Province

Tehran

#### Postal code

1617763141

#### Phone

+98 21 7343 3000

#### Email

info@ehmc.ir

### 2

#### Recruitment center

#### Name of recruitment center

Akhtar hospital

#### Full name of responsible person

Saman Asadi

#### Street address

Sharifi manesh Ave., Elahyeh

#### City

Tehran

#### Province

Tehran

#### Postal code

1964714953

#### Phone

+98 21 2200 1072

#### Email

akhtarhospital@sbmu.ac.ir

## 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

#### City

Tehran

#### Province

Tehran

#### Postal code

1134845763

#### Phone

+98 21 23871

#### Email

info@sbmu.ac.ir

#### 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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Pain clinic, Imam Hossein hospital, Shahid Madani Ave., Imam Ali Blvd.

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**Province**

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**Postal code**

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asadisa60@gmail.com

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mehrdad Taheri

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

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**Person responsible for updating data****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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**Email**

asadisa60@gmail.com

**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**