Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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, asa 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: Proloterapy, 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

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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 teddinopathy
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 restriced 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 prolethropopy, 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 begining 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

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2

Recruitment center

Name of recruitment center

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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

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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
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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