Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

A Comparative Study of the Effect of Two Concentrations of Dextrose Injection (12.5% And 25%) on Pain and Function of Patients with Rotator Cuff Tendinopathy of The Shoulder

Protocol summary

Study aim
Evaluatiojn the effect of injection of 12.5% and 25% dextrose prolotherapy under ultrasound guidance on pain and function in rotator cuff tendinopathy

Design
Semi-experimental clinical trial with control group, with parallel groups, unblinded, computerized randomization, phase 3 on 66 patients

Settings and conduct
Selection of participants from people who come to the sports medicine department of Imam Hospital due to shoulder pain First group: injection of 2 ml of 25% dextrose prolotherapy solution (containing 1 ml of 50% dextrose and 1 ml of 2% lidocaine) in the clinic Second group: injection of 2 ml of 12.5% Prolotherapy dextrose solution (containing 0.5 ml of 50% dextrose and 1.5 ml of 2% lidocaine) in the clinic Control group: home-based exercise therapy

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Adults (over 20 years) Chronic shoulder pain for more than six months Shoulder ultrasound showing chronic tendinopathy of the supraspinatus tendon The average intensity of shoulder pain is more than 3 points on the ten-point Visual Analog Scale Exclusion Criteria: Associated with adhesive capsulitis Shoulder joint replacement Shoulder surgery or arthroscopy of the injured shoulder within the past year Any kind of injection in the shoulder joint within the last three months. Neurological disease that causes weakness on the affected side Impaired cognitive function

Intervention groups
First group: injection of 2 ml of 25% dextrose prolotherapy solution (containing 1 ml of 50% dextrose and 1 ml of 2% lidocaine) Second group: injection of 2 ml of 12.5% Prolotherapy dextrose solution (containing 0.5 ml of 50% dextrose and 1.5 ml of 2% lidocaine) Control group: exercise therapy

Main outcome variables
Primary outcome: mean score in shoulder pain and disability index Secondary outcomes: shoulder active range of motion, supraspinatus tendon thickness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230821059204N2**
Registration date: **2023-10-12, 1402/07/20**
Registration timing: **prospective**

Last update: **2023-10-12, 1402/07/20**
Update count: **0**

Registration date
2023-10-12, 1402/07/20

Registrant information

Name
Hanieh Ahmadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-22, 1402/07/30

Expected recruitment end date
2024-03-19, 1402/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Comparative Study of the Effect of Two Concentrations of Dextrose Injection (12.5% And 25%) on Pain and Function of Patients with Rotator Cuff Tendinopathy of The Shoulder

Public title
Effect of Dextrose Injection in Rotator Cuff Tendinopathy of The Shoulder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adults (over 20 years) Chronic shoulder pain for more than six months Shoulder ultrasound of the supraspinatus tendon showing chronic tendinopathy such as a tear or tendinosis The average intensity of shoulder pain is more than 3 points on the ten-point Visual Analog Scale (VAS) Agreeing and complying with our study protocol The possibility of signing an informed consent form
Exclusion criteria:
Associated with adhesive capsulitis and limited range of motion of the shoulder Shoulder joint replacement Shoulder surgery or arthroscopy of the injured shoulder within the past year Injection of steroid, hyaluronic acid or platelet-rich plasma or any type of prolotherapy injection in the shoulder joint within the last three months Neurological disease that causes weakness on the affected side Impaired cognitive function and inability to complete the questionnaire Concurrent participation in another clinical trial
Age
From **20 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done using computer generated random numbers. Based on the selected numbers, the participants will be assigned to a 12.5% hypertonic dextrose prolotherapy group, another 25% hypertonic dextrose prolotherapy group, and a control group of exercise therapy.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
In the first group, 2 ml of 25% dextrose Prolotherapy solution (containing 1 ml of 50% dextrose and 1 ml of 2% lidocaine) and in the second group 2 ml of 12.5% dextrose Prolotherapy solution (containing 0.5 ml of 50% dextrose and 1.5 ml of 2% lidocaine) will be injected. The control group will be exercise therapy.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences, Imam Hospital
Street address
Serah Joibar, the beginning of Vali Asr Highway, the headquarters of Mazandaran University of Medical Sciences and Health Services
City
Sari
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Postal code
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Approval date
2023-04-19, 1402/01/30
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1402.14941

Health conditions studied

1

Description of health condition studied
Rotator cuff tendinopathy of the shoulder
ICD-10 code
S46.0
ICD-10 code description
Injury of muscle(s) and tendon(s) of the rotator cuff of shoulder

Primary outcomes

1

Description
Average score in the Shoulder Pain and Disability Index (SPADI) of the injured shoulder
Timepoint
At the beginning of the study before the start of the intervention and at the end of the second and sixth weeks after the intervention
Method of measurement

The Shoulder Pain and Disability Index (SPADI) is a self-administered assessment tool used to measure shoulder pain and disability. It has five pain items and eight disability items measured on the Visual Analogue Score. Pain and disability subscales are calculated as the mean of the corresponding items on a 0-100 scale, with the highest score indicating the most severe pain and disability. In this study, the total outcome score used for statistical analysis will be calculated as the sum of pain and disability subscales.

Secondary outcomes

1

Description
Active range of motion of the shoulder
Timepoint
At the beginning of the study before the start of the intervention and at the end of the second and sixth weeks after the intervention
Method of measurement
Active shoulder range of motion, i.e., forward flexion, internal rotation, external rotation, and abduction in standing position, will be assessed using a goniometer. Patients will move their shoulders slowly until they reach an angle at which pain is felt, and this movement will be performed three times to record the average value of the angle.

2

Description
Supraspinatus tendon thickness
Timepoint
At the beginning of the study before the start of the intervention and at the end of the second and sixth weeks after the intervention
Method of measurement
Using ultrasound, the maximum thickness of the supraspinatus tendon will be measured in millimeters.

Intervention groups

1

Description
Intervention group 1: The injection will be performed under ultrasound guide by a sports medicine specialist. Patients will maintain an upright sitting position with shoulder extension, arm flexion, and hand to hip touch to obtain a longitudinal view of the supraspinatus tendon. A prolotherapy injection session will be performed under ultrasound guide in aseptic conditions using a 23-G needle to the insertion site of the supraspinatus tendon. In the first group, 2 ml of 25% Prolotherapy dextrose solution (containing 1 ml of 50% dextrose and 1 ml of 2% lidocaine) will be injected.
Category
Treatment - Drugs

2

Description
Intervention group 2: The injection will be performed under ultrasound guide by a sports medicine specialist. Patients will maintain an upright sitting position with shoulder extension, arm flexion, and hand to hip touch to obtain a longitudinal view of the supraspinatus tendon. A prolotherapy injection session will be performed under ultrasound guide in aseptic conditions using a 23-G needle to the insertion site of the supraspinatus tendon. In the first group, 2 ml of 12.5% Prolotherapy dextrose solution (containing 0.5 ml of 50% dextrose and 1.5 ml of 2% lidocaine) will be injected.
Category
Treatment - Drugs

3

Description
Control group: The control group will be given exercise therapy, which exercises will be given to the patient in a booklet, and they will be taught in each visit that the exercises in the first week include correcting the position of the scapula and the shrug of the scapula; in the second week includes external rotation at zero degrees; In the third week, it includes internal rotation at 0 degrees, and in the fourth week, it includes boat movement at 45 degrees, boat movement at 90 degrees, anterior shoulder stretching and trunk stretching in a sitting position.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Sports Medicine, Mostafavian Clinic, Sari Imam Khomeini Hospital
Full name of responsible person
Hanieh Ahmadi
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Sports Medicine Department, Mostafavian Clinic, Razi No. 3 Alley, Razi St., Sari
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Sponsors / Funding sources

1

Sponsor
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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
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Hanieh Ahmadi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be 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