

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Functional Improvement and Pain Relief in Frozen Shoulder after treatment of Prolotherapy and Exercise with Exercise alone :RCT

Protocol summary

Study aim

Comparison of performance, pain improvement and range of motion in patients with frozen shoulder referring to Shohadaye Tajrish physical medicine clinic in two groups receiving Prolotherapy and exercise and the group receiving exercise

Design

The clinical trial had a control group, with parallel, double-blind groups, randomized, on 40 patients. For randomization, rand function of Excel software was used.

Settings and conduct

40 patients referred to physical medicine and rehabilitation clinic of Shohada Tajrish Hospital, who have frozen shoulder signs and symptoms, receive written and informed consent based on inclusion and exclusion criteria. Then, the intervention group will be treated with prolotherapy and exercise therapy and the control group will be followed for two weeks and 6 weeks later.

Participants/Inclusion and exclusion criteria

Inclusion criteria include adults with frozen shoulder: Ages 18 to 75 In the first stages of the frozen shoulder (painful phase) (up to 4 months pass since the onset of the disease) Have the consent and willingness to participate in the study. Exclusion criteria: Patients with a history of recent shoulder fractures and trauma, history of inflammation and infection of the joint or active tendonitis, any bone disease of the shoulder, physical history of therapy or any intra-joint injection involved during the past three months, history of NSAID drugs in the last 2 weeks, history of systemic corticosteroid use in the last month, history of shoulder surgery, sensitivity to dextrose or triamcinolone and recurrence of the disease. Shoulder and unwillingness to participate in the study will be excluded.

Intervention groups

The two groups receive Exercise + Prolotherapy and the

group receiving Exercise.

Main outcome variables

Evaluation of ROM, pain rate based on VAS, performance based on oxford shoulder score, prevalence of this disease in different sexes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220403054400N1**

Registration date: **2022-08-31, 1401/06/09**

Registration timing: **registered_while_recruiting**

Last update: **2022-08-31, 1401/06/09**

Update count: **0**

Registration date

2022-08-31, 1401/06/09

Registrant information

Name

zahra safaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2246 5720

Email address

ghazvini_mh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-22, 1401/02/02

Expected recruitment end date

2023-03-10, 1401/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Functional Improvement and Pain Relief in Frozen Shoulder after treatment of Prolotherapy and Exercise with Exercise alone :RCT

Public title

Comparison of Functional Improvement and Pain Relief in Frozen Shoulder after treatment of Prolotherapy and Exercise with Exercise alone :RCT

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

In the first stage of frozen shoulder (in painful phase) (maximum 4 months past the onset of the disease). - Have the consent and willingness to participate in the study.

Exclusion criteria:

In the first stage of frozen shoulder (in painful phase) (maximum 4 months past the onset of the disease). - Have the consent and willingness to participate in the study.

AgeFrom **18 years** old to **75 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample sizeTarget sample size: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

This study is of the type of clinical trial studies that through simple randomization of 40 patients referred to the Physical Medicine and Rehabilitation Clinic of Shahada Tajrish Hospital, Shahid Beheshti University of Medical Sciences, who have signs and symptoms of frozen shoulder based on history and examination. and are in the initial phase of the disease (at most 4 months have passed since the onset of the disease symptoms), they are divided into two arms (through a sealed envelope that was in the form of A and B and the participant in the study did not know the type of intervention) And they will be examined based on the entry and exit criteria of the study. In terms of blinding, in this study, the blinding process will be done for the participant and the data analyst. In this way, after assigning people to the arms, the main researcher will have access to the type of intervention of each person and after collecting the data, the data will be presented

as two groups A and B to the analyst for data analysis.

After analyzing the data, the obtained information will be analyzed by the researcher.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants in the study were divided through a sealed envelope that was in the form of A and B, and the participant in the study did not know the type of intervention, and after assigning people to the arms, the main researcher will have access to the type of intervention of each person Collecting data, the data is presented in two groups, A and B, to the individual analyst for data analysis. After analyzing the data, the obtained information will be analyzed by the researcher.

Placebo

Not 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

Department of Physical Medicine and Rehabilitation, Shohadash Hospital , Tajrish Street

City

tehran

Province

Tehran

Postal code

1989934148

Approval date

2022-02-18, 1400/11/29

Ethics committee reference number

IR.SBMU.MSP.REC.1400.747

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

Frozen shoulder

ICD-10 code

M75.0

ICD-10 code description

Adhesive capsulitis of shoulder

Primary outcomes

1

Description

Comparison of the effect of prolotherapy with exercise and exercise alone in reducing pain based on VAS, and comparing the performance based on Oxford shoulder score and range of motion of internal and external rotation and flexion by goniometer, investigating the prevalence of frozen shoulder based on sex

Timepoint

2 weeks & 6 weeks

Method of measurement

Comparison of the effect of prolotherapy with exercise and exercise alone in reducing pain based on Visual Analogue Scale, and comparison of Oxford shoulder score and range of motion of internal and external rotation and flexion by gunometer, evaluation of the prevalence of frozen shoulder based on sex

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will be treated with intra-articular injection of 5 cc dextrose solution 50% with 2.5 cc lidocaine and 2.5 cc of distilled water with ultrasound guid and ROM exercise and stretching exercise will be taught to the patient.

Category

Treatment - Drugs

2

Description

Control group: In case of pain, the patient can use acetaminophen 500mg without codeine.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada tajrish hospital

Full name of responsible person

Dariush elyiaspour

Street address

Department of Physical Medicine and Rehabilitation,
Shohadash Hospital ,Tajrish Street

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Pr_shohada@sbmu.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin zarghi

Street address

5th Floor, Building 2, Shahid Beheshti University of
Medical Sciences, Shahid Arabi Street, Yemen Street ,
Shahid Chamran Highway

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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

Zahra Safaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

Zahra Safaei

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City

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Province

Tehran

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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

This study will be conducted blinding process for outcome assessor and analyst. In this way, after assigning people to the arms, only the main researcher will have access to the type of intervention of each individual and the type of intervention on the questionnaire will be as options A (main intervention) and B (control intervention) and the analyst will report the results as differences between groups A and B after the analysis and the main researcher will ultimately determine the type of intervention. After data collection, data will be analyzed by SPSS ver. 25 statistical software. Continuous quantitative variables will be reported by central dispersion indices (mean and standard deviation). K-S test will also be used to determine the normality of data distribution. Student T Test and Chi Square Test will be used for analysis between groups. $P < 0.05$ will be considered as a significant level for all tests.

When the data will become available and for how long

Start access period 6 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

To refer the contents

From where data/document is obtainable

zahasafaei1994@yahoo.com Zahra Safaei 09122937180
00982122465720 Tehran-Tajrish Square - Shohadaye
Tajrish Hospital

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

After receiving the request and not inconsistent with the information received, the data will be sent to the applicant within 2-3 business days.

Comments

