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)

Phone
+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.
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target 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

City
Tehran

Province
Tehran

Postal code
1989934148

Phone
+98 21 25719

Email
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

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 2243 9781

Fax
+98 21 2243 9981

Email
Mpajouhesh@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
Zahra Safaei

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Physical Medicine

Street address
Department of Physical Medicine and Rehabilitation, Shohadash Hospital ,Tajrish Street
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 25719
Email
zahrasafaei1994@yahoo.com

Person responsible for scientific 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
Street address
Department of Physical Medicine and Rehabilitation, Shohadash Hospital , Tajrish Street
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 25719
Email
zahrasafaei1994@yahoo.com

Person responsible for updating data

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
Street address
Department of Physical Medicine and Rehabilitation ,Shohadash Hospital ,Tajrish Street
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 25719
Email
zahrasafaei1994@yahoo.com

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
zahrasafaei1994@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