Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A Randomized Controlled Trial Comparing Platelet-Rich Plasma, Corticosteroid Injections, and Combination Therapy in Patients with Idiopathic and Diabetic Adhesive Capsulitis

Protocol summary

Study aim

To compare the effectiveness of intra-articular platelet rich plasma, corticosteroid injections, and their combination on pain reduction, functional improvement, and shoulder range of motion in patients with idiopathic or diabetic adhesive capsulitis.

Design

Randomized, parallel group, superiority clinical trial with three intervention arms, stratified by etiology (idiopathic or diabetic), with blinded outcome assessment and allocation concealment.

Settings and conduct

A randomized clinical trial conducted at a private clinic in shahrood [City], Iran, from June 2023 to January 2024.

Participants/Inclusion and exclusion criteria

Inclusion: Age 30–75; unilateral adhesive capsulitis confirmed clinically; shoulder pain ≥1 month; ≥one-third ROM loss; normal radiography and proximal upper limb neurology; no prior pain-relief intervention. Exclusion: Previous intra-articular injection; unwillingness; glenohumeral pathology or other shoulder pain causes; trauma, surgery, or Sudek's atrophy; injection within 6 months; NSAID use in 7 days; blood disorders; antiplatelet/anticoagulant therapy; thyroid/lung disease; neoplastic disorders; pregnancy/breastfeeding; uncontrolled diabetes; neurological, rheumatological, malignant, or immunodeficiency disease; substance abuse; cervical radiculopathy.

Intervention groups

Group 1: Intra-articular injection of platelet rich plasma (PRP) prepared from 20 mL autologous blood, activated with thrombin, mixed with lidocaine and distilled water (total 20 mL). Group 2: Intra-articular injection of triamcinolone (40 mg/mL) with lidocaine and distilled water (total 20 mL). Group 3: Intra-articular injection of PRP plus triamcinolone (40 mg/mL) with lidocaine and distilled water (total 20 mL).

Main outcome variables

Primary outcomes: Shoulder pain (VAS); shoulder function/disability (SPADI); shoulder range of motion in all planes (goniometer).

General information

Reason for update

Acronym

PRP-CS-FS

IRCT registration information

IRCT registration number: **IRCT20250718066536N2**
Registration date: **2025-08-18, 1404/05/27**
Registration timing: **prospective**

Last update: **2025-08-18, 1404/05/27**
Update count: **0**

Registration date

2025-08-18, 1404/05/27

Registrant information

Name

Soheil Shahramirad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3740 8566

Email address

soheil.rad2019@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2025-12-22, 1404/10/01

Actual recruitment start date
2025-09-23, 1404/07/01
Actual recruitment end date
2025-12-22, 1404/10/01
Trial completion date
2025-12-22, 1404/10/01

Scientific title
A Randomized Controlled Trial Comparing Platelet-Rich Plasma, Corticosteroid Injections, and Combination Therapy in Patients with Idiopathic and Diabetic Adhesive Capsulitis

Public title
Comparing PRP, Corticosteroid, and Combined Therapy for Frozen Shoulder in People With or Without Diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 30 and 75 years; unilateral frozen shoulder diagnosed by physical examination and clinical evaluation; shoulder pain persisting for at least one month; loss of at least one-third of the range of motion in various shoulder movements; normal shoulder joint radiography; normal neurological examination of the proximal upper limb; and no prior pain relief interventions for the affected shoulder.
Exclusion criteria:
History of previous treatments aimed at reducing shoulder pain, such as intra-articular injections; unwillingness to continue participation in the study; any intra-articular pathology of the glenohumeral joint or shoulder pain due to other causes; history of trauma or shoulder surgery; clinical evidence of Sudeck's atrophy syndrome; injection in the affected shoulder joint within the past six months; use of non-steroidal anti-inflammatory drugs in the last seven days; presence of blood disorders or current antiplatelet or anticoagulant treatment; presence of thyroid or lung disorders, particularly emphysema and chronic bronchitis; neoplastic disorders; pregnancy or breastfeeding; uncontrolled diabetes; neurological, rheumatological, malignant, or immunodeficiency diseases; history of drug or alcohol use or addiction; and cervical radiculopathy.
Age
From **30 years** old to **78 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **100**
Actual sample size reached: **82**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was performed using simple randomization at the individual level. The allocation process was carried out by an independent person who was not involved in the intervention. The random sequence list was generated using statistical software and random number generation. Allocation sequences were kept in opaque, sealed envelopes and were opened at the time of each participant's enrollment to ensure allocation concealment. Upon enrollment, participants were assigned to one of the three treatment groups according to the random sequence.
Blinding (investigator's opinion)
Single blinded
Blinding description
The outcome assessor was blinded to the group allocation. The person who recorded the outcome data was different from the intervention provider and was not aware of the participants' assigned treatment groups.
Placebo
Not used
Assignment
Parallel
Other design features
Randomized controlled trial with three parallel intervention groups. Outcome assessor blinded to group allocation.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University, Shahrood Branch
Street address
No. [—], University Blvd., Islamic Azad University, Shahrood Branch, Shahrood, Semnan Province, Iran
City
Shahrood
Province
Semnan
Postal code
4318936199
Approval date
2025-05-05, 1404/02/15
Ethics committee reference number
IR.IAU.SHAHROOD.REC.1404.001

Health conditions studied

1

Description of health condition studied
Adhesive Capsulitis (Frozen Shoulder), Idiopathic and Diabetic
ICD-10 code
M75.0 – Ad
ICD-10 code description
Adhesive capsulitis of shoulder

Primary outcomes

1

Description
Change in shoulder pain, disability (SPADI, VAS), and range of motion measured at baseline, 4 weeks, and 8 weeks after treatment.
Timepoint
Baseline, 4 weeks, and 8 weeks after intervention
Method of measurement
Shoulder Pain and Disability Index questionnaire

Secondary outcomes

1

Description
Change in pain intensity score measured by the Visual Analogue Scale from baseline to 8 weeks after intervention
Timepoint
Baseline, 4 weeks, and 8 weeks after intervention
Method of measurement
Measured using a goniometer for shoulder range of motion

Intervention groups

1

Description
Intervention group: Single intra-articular injection of 4 mL platelet-rich plasma (activated with thrombin, 1:10) mixed with 4 mL of 2% lidocaine and diluted with distilled water to a final volume of 20 mL. The injection was administered into the glenohumeral joint (15 mL) and the subacromial space (5 mL) via posterior approach.
Category
Treatment - Drugs

2

Description
Intervention group: Single intra-articular injection of 1 mL triamcinolone acetonide (40 mg/mL) with 4 mL platelet-rich plasma and 4 mL of 2% lidocaine, diluted with distilled water to a final volume of 20 mL. The injection was administered into the glenohumeral joint (15 mL) and the subacromial space (5 mL) via posterior approach.
Category
Treatment - Drugs

3

Description
Control group: Single intra-articular injection of 2 mL triamcinolone acetonide (40 mg/mL) with 4 mL of 2% lidocaine, diluted with distilled water to a final volume of 20 mL. The injection was administered into the glenohumeral joint (15 mL) and the subacromial space (5 mL) via posterior approach.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Medicine, Shahrood Branch, Islamic Azad University private clinic
Full name of responsible person
Saeed Enayati
Street address
No. 1, North Ferdowsi Street, Faculty of Medicine, Shahrood Branch, Islamic Azad University, Shahrood, Semnan Province, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Nasrin Rezavian-zadeh
Street address
No. 1, North Ferdowsi Street, Faculty of Medicine, Shahrood Branch, Islamic Azad University, Shahrood, Semnan Province, Iran
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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
Islamic Azad University
Proportion provided by this source
5

Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Saeed Enayati
Position
Faculty Member, Faculty of Medicine
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
Street address
No. 1, North Ferdowsi Street, Faculty of Medicine, Shahrood Branch, Islamic Azad University, Shahrood, Semnan Province, Iran
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Person responsible for updating data

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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
An anonymized individual participant dataset, including demographic variables, primary and secondary outcome measures, and other study-related data, along with the data dictionary and statistical analysis codes, will be provided in standard electronic formats (CSV or SPSS). All data will be reviewed and de-identified prior to release."
When the data will become available and for how long
Access to the data will be available starting 6 months after publication of the main article in a peer-reviewed journal and will continue for 5 years after the publication

date."

To whom data/document is available

Access will be granted to researchers affiliated with universities, recognized research institutions, or healthcare organizations who have an approved research proposal."

Under which criteria data/document could be used

"The data may be used solely for secondary analyses related to the study topic and for the purpose of publishing results in reputable scientific journals. Use of the data requires signing a data use agreement and adherence to ethical and confidentiality considerations."

From where data/document is obtainable

Requests should be addressed to Dr. Saeed Enayati, Faculty of Medicine, Islamic Azad University, Shahrood Branch. Email: [your email], Tel: +98 23 [phone number]."

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

The requesting researcher must submit a formal application along with their research proposal. The request will be reviewed by the university's scientific/ethical committee, and upon approval, a data use agreement will be signed. Following completion of the process, the data will be delivered securely and in encrypted form within 4 weeks

Comments

Data transfer will be carried out electronically through secure platforms only. Any unauthorized use or dissemination without written permission is prohibited."