Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of exercise therapy and Platelet Rich Plasma injection in pain and symptoms in people over 40 that suffer from subacromial impingement syndrome

Protocol summary

Summary

The aim of this study is comparing exercise therapy and PRP injection in subacromial impingement syndrome . It is a randomized controlled trial . 42 patients over 40 with complaint of shoulder pain at least 3 months , have positive finding in physical exam forshoulder impingement syndrome , whose diagnose has been proved with shoulder MRI are included in the study . 42 participants are randomly assigned to each of the 2 treatment groups : group 1 exercise therapy group 2 PRP injection . Subjects in the exercise group are receive an individualized exercise program that is developed and supervised by a physician once a week . The patients are asked to exercise every day at home for 3 months according to the booklet . In second group , approximately 10 cc of venous blood is drawn from the patient and is prepared according to the Regenlab manufacturer`s guidelines, then the 2 cc accessed PRP is injected under ultrasound guidance using a lateral approach . Before and after 1, 3, 6 months of treatment all patients are evaluated to check the range of motion of shoulder joint , strength of rotator cuff muscles . patients complete DASH and WORC questionnaire to evaluate the pain and function . If the WORC and DASH scores remain unchanged in the PRP group until the last 1 month , another PRP injection is repeated . MRI is performed in all cases at the sixth month .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201308064409N3**
Registration date: **2013-08-30, 1392/06/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-08-30, 1392/06/08

Registrant information

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Science

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of exercise therapy and Platelet Rich Plasma injection in pain and symptoms in people over 40 that suffer from subacromial impingement syndrome

Public title

Exercise therapy and Platelet Rich Plasma injection in

shoulder pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : A shoulder pain that has been lasted for more than three months , age over 40 exclusion criteria : Radicular pain , Other causes of shoulder pain such as the frozen shoulder, the history of shoulder surgery during 6 months ago , The inflammation disorders such as ; Rheumatoid arthritis , Fibromyalgia , Polymyalgia rheumatica . Full thickness tear of rotator cuff tendon , Ligamentous laxity or shoulder dislocation (a positive sulcus test or apprehensive test)

Age

From **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran Uneversity of Medical Sciences

Street address

Iran University of Medical Science , Hemat highway

City

Tehran

Postal code

1417614411

Approval date

2013-04-19, 1392/01/30

Ethics committee reference number

21391-89429

Health conditions studied

1

Description of health condition studied

subacromial impingement syndrome

ICD-10 code

M75.1 ,M75

ICD-10 code description

Rotator cuff syndrome, Impingement syndrome of shoulder , Bursitis of shoulder

Primary outcomes

1

Description

Range Of Motion of shoulder joint

Timepoint

Before intervention and 1,3,6 months after intervention

Method of measurement

goniometer

2

Description

strength of shoulder muscles

Timepoint

Before intervention and 1,3,6 months after intervention

Method of measurement

Muscle manual test (MMT)

3

Description

WORC - score

Timepoint

Before intervention and 1,3,6 months after intervention

Method of measurement

WORC Questionnaire

4

Description

DASH- score

Timepoint

Before intervention and 1,3,6 months after intervention

Method of measurement

DASH Questionnaire

5

Description

Rotator cuff tendon pathology (supra spinatus ,infra spinatus,teres minor, sub scapularis)

Timepoint

Before intervention and 6 months after intervention

Method of measurement

MRI

Secondary outcomes

1

Description

Acromiohumeral distance

Timepoint

Before intervention , 6 months after intervention

Method of measurement

MRI

2

Description

Sub acromion sub deltoid bursea pathology

Timepoint

Before intervention , 6 months after intervention

Method of measurement

MRI

3

Description

Glenohumeral fluid collections

Timepoint

Before intervention , 6 months after intervention

Method of measurement

MRI

4

Description

Acromion shape

Timepoint

Before intervention , 6 months after intervention

Method of measurement

MRI

Intervention groups

1

Description

In intervention group : 2 cc PRP is prepared according to the (Regenlab) manufacturar`s guidelines then is injected under ultrasound guidance using a lateral approach.If the WORC and DASH scores remain unchanged until the last 1 month another PRP injection is repeated

Category

Treatment - Drugs

2

Description

Control group : The patients are received an individualized exercise program that is developed and supervised by a physician once a week. The patients are asked to exercise everyday for 3 months at home according to the booklet

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul akram hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

Dr.abbas motevalian

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Vice-chanellor for research ,Headquarter for Iran University of Medical Sciences , Hemat highway

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty