Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

A Comparative Study of the Efficacy of single and double Centrifuged platelet rich plasma and placebo (normal saline injection) on Pain, ROM and Physical Function of Patients with Knee Osteoarthritis: A Double Blinded Controlled Randomized Trial with a Three-Month Follow –up

Protocol summary

Study aim
Comparison of the efficacy of single and double Centrifuged platelet rich plasma and placebo (normal saline injection) on pain, range of motion and function of patients with osteoarthritis of the knee

Design
A Double Blinded Controlled Randomized Trial, with three arm parallel groups with 15 patients in each groups. Block randomization will be used.

Settings and conduct
In patients with knee osteoarthritis referred to Rasoul Akram Hospital based on inclusion criteria, after obtaining written consent with random allocation, in one of the three treatment groups, single and double centrifuged of platelet-rich plasma and group Placebo will be divided. Patients will be evaluated at the beginning of the intervention, one month and three months later with VAS criteria, WOMAC questionnaire, knee range of motion and functional tests. Patients, assessor Clinician and statistical analyzer are blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with grade 2 or 3 knee osteoarthritis by the Kellgren and Lawrence criteria with 50-75 years old and body mass index equal to or less than 35. They have persistent knee pain for at least six months and with an intensity of at least 4 according to VAS score; Exclusion criteria: The patient has a history of intra-articular injection in the knee during the last six months, or neuromuscular diseases, history of acute traumatic injury, surgery over the last year, bone implants, a new fracture in the lower extremities during the last year, malignant tumors and physiotherapy programs during the last three months.

Intervention groups
Intervention group 1: Injection of platelet-rich plasma extracted single centrifuged. Intervention group 2: Injection of platelet-rich plasma extracted double centrifuged. Control group: Normal saline injection as a placebo group

Main outcome variables
Pain and function of the knee

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140907019073N5**
Registration date: **2021-07-10, 1400/04/19**
Registration timing: **prospective**

Last update: **2021-07-10, 1400/04/19**
Update count: **0**

Registration date
2021-07-10, 1400/04/19

Registrant information

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Name of organization / entity
IUMS

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative Study of the Efficacy of single and double Centrifuged platelet rich plasma and placebo (normal saline injection) on Pain, ROM and Physical Function of Patients with Knee Osteoarthritis: A Double Blinded Controlled Randomized Trial with a Three-Month Follow –up

Public title

Comparison of the efficacy of platelet rich plasma injection which extracted by two methods and placebo on pain, range of motion and function of patients with osteoarthritis of the knee

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with grade 2 or 3 primary osteoarthritis of the knee as determined by the Kellgren and Lawrence criteria. (Associated with knee pain, morning stiffness less than 30 minutes, crepitus on movement and radiological signs of osteoarthritis include joint space loss, subchondral bone sclerosis and the formation of osteophytes in knee) Patients aged 50-75 years. Patients who have persistent knee pain for at least six months and with an intensity of at least 4 according to the VAS scale in activities such as going up and down stairs, sitting for long periods and squatting. Patients who are able to walk independently for at least 30 meters. Patients with a body mass index equal to or less than 35. The patient has full consent to participate in the study. The patient has a balanced mental state.

Exclusion criteria:

The patient has a history of intra-articular injection in the knee during the last six months. The patient has neuromuscular diseases. The patient has a history of acute traumatic injury to other ligaments and structures of the knee joint with the approval of a specialist. The patient has a history of surgery or previous injury in the knee and other lower limb joints over the last year. The patient has bone implants. The patient has a new fracture in the lower extremities during the last year. The patient has malignant tumors. The patient has participated in exercise therapy and physiotherapy programs during the last three months.

Age

From **50 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of patients in treatment groups randomly using blockade with six blocks in one of the treatment groups will be as follows. A table of random numbers will be used to assign the blocks. For this purpose, one of the blocks is selected by chance and the patients are injected according to the proposed group in the block, respectively, and then the blocks are moved forward in sequence, and this process continues until the end of sampling. Group A is single Centrifuged group, group B is double Centrifuged, group C is a placebo group (normal saline). A:SS (single spin) B:DS (double spin) C: P (placebo) -Block1: AABBCC -Block2: ABCABC -Block3: CCBBAA -Block4: CBACBA -Block5: ABCCBA -Block6: CBAABC

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the following people will be blind of the treatment groups of patients: Patients in the study only know that they are being injected and will not know the number of centrifuges performed. Also, in this study, injectable interventions are performed under the supervision of a sports medicine specialist, who is not aware of the number of centrifuges performed and only injects the solution into the joint. - Assessor Clinician: Assessments before and after interventions in the Sports Medicine Clinic will be performed by a sports medicine resident other than the researcher who does not know the presence of patients in the groups. - Statistical Consultant and Analyzer: Analysis of research data will be performed by a statistical consultant who is not aware of patient groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Iran University of Medical sciences, south side of Hemmat highway, Tehran, Iran.

City

Tehran

Province
Tehran
Postal code
1449614535
Approval date
2020-12-15, 1399/09/25
Ethics committee reference number
IR.IUMS.FMD.REC.1399.611

Health conditions studied

1

Description of health condition studied
Knee Osteoarthritis
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Knee function with WOMAC(Western Ontario and McMaster Universities Osteoarthritis Index) scale
Timepoint
Before the intervention and one month and three months after the intervention
Method of measurement
Western Ontario and McMaster Universities Osteoarthritis Index questionnaire

2

Description
Feeling knee pain by Visual Analogue Scale (VAS)
Timepoint
Before the intervention and one month and three months after the intervention
Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

1

Description
Knee range of motion
Timepoint
Before the intervention, one month and three months after the intervention
Method of measurement
Goniometry

2

Description
Timed Up & Go test: The ability of a person to get up from a chair over a distance of 3 meters and return to the chair
Timepoint
Before the intervention, one month and three months after the intervention
Method of measurement
Stopwatch (seconds)

3

Description
Six Minute Walk test: The person's ability to walk for 6 minutes
Timepoint
Before the intervention, one month and three months after the intervention
Method of measurement
Distance measurement (meter)

4

Description
Stair climbing test: The ability of a person to climb stairs to reach the stage of pain or fatigue
Timepoint
Before the intervention, one month and three months after the intervention
Method of measurement
The number of steps taken

Intervention groups

1

Description
Intervention group 1: The Group which treated by injection of platelet-rich plasma extracted single centrifuged. Preparation of PRP solution and injection will be done in the sports medicine clinic of Hazrat Rasool Akram Hospital. Patients are asked to discontinue anticoagulants and aspirin (if any) with their doctor's permission the week before the injection. To prepare PRP, kits (Arya Mabna Tashkis Corporation, RN: 312569, Rooyagen Kit) are used which have a completely sterile pack. To prepare the injection solution, 35 cc of intravenous blood from the upper limb was taken from the patients by a 50 cc syringe in which 5 cc of anticoagulant solution had already been drawn, and with the help of an 18 G needle-shaped blood transfusion adapter without any pressure on the piston into the four Sterile tube is transferred. At the same time, about 0.5 cc of the patient's blood will be sent to the laboratory of Hazrat Rasool Akram Hospital to check the amount of blood cells. All 4 tubes are filled in balance and placed in a centrifuge and rotated at 1600 RPM for 10 minutes, then they are taken out. In the group, the upper half of the isolated plasma centrifuge will be removed from all four tubes and only the lower half of the plasma will be used for injection. About 5 cc of the PRP solution prepared for injection into the 5 cc syringe is drawn with a 14G needle tip and about 0.5 cc is separated again to be sent to the laboratory. In case of pain, the patient can take acetaminophen without codeine and is not allowed to take aspirin for 10 days. It is recommended that

patients don't put weight on injected knee and doing strenuous activity for 48 hours after the injection. One of the most important ways to treat patients with osteoarthritis of the knee is to use exercise therapy. A common exercise protocol will be prescribed for patients with osteoarthritis of the knee participating in this study.

Category

Treatment - Other

2

Description

Intervention group 2: The Group which treated by injection of platelet-rich plasma extracted double centrifuged. Preparation of PRP solution and injection will be done in the sports medicine clinic of Hazrat Rasool Akram Hospital. Patients are asked to discontinue anticoagulants and aspirin (if any) with their doctor's permission the week before the injection. To prepare PRP, kits (Arya Mabna Tashkis Corporation, RN: 312569, Rooyagen Kit) are used which have a completely sterile pack. To prepare the injection solution, 35 cc of intravenous blood from the upper limb was taken from the patients by a 50 cc syringe in which 5 cc of anticoagulant solution had already been drawn, and with the help of an 18 G needle-shaped blood transfusion adapter without any pressure on the piston into the four Sterile tube is transferred. At the same time, about 0.5 cc of the patient's blood will be sent to the laboratory of Hazrat Rasool Akram Hospital to check the amount of blood cells. All 4 tubes are filled in balance and placed in a centrifuge and rotated at 1600 RPM for 10 minutes, then they are taken out. In this group, the plasma separated by the first centrifuge are drawn into the tubes and poured into two other 10 cc sterile tubes inside the box containing 0.6 cc of preservative with anti-platelet aggregation solution. It is then re-inserted and centrifuged at 3500RPM for 6 minutes. Then 3 cc end of each 2 tubes after removing the upper plasma is drawn by 5 cc syringe with 14G needle head and about 0.5 cc is separated for sending to laboratory. In case of pain, the patient can take acetaminophen without codeine and is not allowed to take aspirin for 10 days. It is recommended that patients don't put weight on injected knee and doing strenuous activity for 48 hours after the injection. One of the most important ways to treat patients with osteoarthritis of the knee is to use exercise therapy. A common exercise protocol will be prescribed for patients with osteoarthritis of the knee participating in this study.

Category

Treatment - Other

3

Description

Control group: Therapeutic group with normal saline injection as a placebo group. In this group, 5 cc of normal saline will be injected as a placebo after blood sampling. In case of pain, the patient can take acetaminophen without codeine and is not allowed to take aspirin for 10 days. It is recommended that patients don't put weight on injected knee and doing strenuous activity for 48 hours after the injection. One of the most important ways to treat patients with osteoarthritis of the knee is to use exercise therapy. A common exercise protocol will be prescribed for patients with osteoarthritis of the knee participating in this study.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool-e-Akram Hospital

Full name of responsible person

Ali Mazaherinezhad

Street address

Rasool-e-Akram Hospital, Niyayesh Ave, Sattarkhan St., Tehran, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Mazaheri.a @iums.ac.ir

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 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

Iran University of Medical Sciences

Full name of responsible person

Ali Mazaherinezhad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

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Person responsible for scientific inquiries

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Position

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Latest degree

Specialist

Other areas of specialty/work

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

IPD collection for the primary and secondary outcomes

When the data will become available and for how long

Immediately after publication

To whom data/document is available

People working in academic institution

Under which criteria data/document could be used

The result of further analysis may not be presented to public without permission

From where data/document is obtainable

Mazaherinezhad.a@iums.ac.ir

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

A reasonable request from an academic source will be

responded within 10 working days

Comments