Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

A Comparative Study of changes in knee MRI findings after single and double Centrifuged platelet rich plasma and placebo (normal saline injection) in Patients with Knee Osteoarthritis: A Controlled Randomized Trial with a six-Month Follow –up

Protocol summary

Study aim
A Comparative Study changes in knee Magnetic resonance imaging(MRI) findings after single and double Centrifuged platelet rich plasma and placebo (normal saline injection) in Patients with Knee Osteoarthritis

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

Settings and conduct
The study site is the Department of Sports Medicine and Radiology at Rasoul Akram Hospital in Tehran. The study population is patients with osteoarthritis of the knee.This study is double-blind. Patients in this study are not blind.The sports medicine specialist and the researcher are not aware of the number of centrifuges performed and the MRIs of the patients. The analyzer is also not aware of patient groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with grade 2 or 3 knee osteoarthritis; age of 50-75 years old; body mass index equal to or less than 35; persistent knee pain for at least six months and with an intensity of at least 4 according to VAS score. Non-inclusion criteria: The patient with history of intra-articular injection in the knee during the last 6 months; neuromuscular diseases; history of acute traumatic injury or surgery during the past year; bone implants; a new fracture in the lower extremities during the last year; malignant tumors; physiotherapy programs during the last three months.

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

Main outcome variables
MRI changes; pain; knee function; range of motion; TUG, 6MW and STAIR CLIMBING tests

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20211016052782N1**
Registration date: **2021-11-22, 1400/09/01**
Registration timing: **prospective**

Last update: **2021-11-22, 1400/09/01**
Update count: **0**

Registration date
2021-11-22, 1400/09/01

Registrant information
Name
mostafa ghadamzadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 2211 3209
Email address
ghadamzadeh.m@iums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-12-06, 1400/09/15
Expected recruitment end date
2022-12-06, 1401/09/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Comparative Study of changes in knee MRI findings after single and double Centrifuged platelet rich plasma and placebo (normal saline injection) in Patients with Knee Osteoarthritis: A Controlled Randomized Trial with a six-Month Follow –up

Public title
The effect of platelet rich plasma on MRI findings among patients with knee osteoarthritis
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 (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 any contraindications for MRI, including aneurysm clips, pacemakers, metal devices in the body, and claustrophobia 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
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation of patients in treatment groups using block randomization method with blocks of size six in one of the treatment groups will be as follows: A table of random numbers will be used to arrange the blocks. For this purpose, one of the blocks is selected by chance using table of random numbers 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. The researcher also does not know which MRI belongs to which injection group - 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. MRI data and changes are also reviewed by two radiologists who are unaware of the patient 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
2021-07-03, 1400/04/12
Ethics committee reference number
IR.IUMS.FMD.REC.1400.236

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 MRI Changes Based on MRI Osteoarthritis Knee Score (MOAKS)
Timepoint
Before the intervention and six months after the intervention
Method of measurement
Using the PACS system

2

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

3

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)

4

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

5

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

6

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)

7

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

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: The Group which treated by injection of platelet-rich plasma extracted single centrifuged. One week before the injection, an MRI of the patient's affected knee is performed at the MRI imaging center of Rasoul Akram Hospital. MRI of the knee will be performed by 1.5 T device with annular coil of the knee and in fat suppressed sequences of coronal, sagittal and axial PD and T1, T2 sagittal before and 6 months after treatment. MRI will be performed by two radiologists with experience in organ imaging who are unaware of the patient group and will examine and record cartilage thickness, joint space narrowing, the presence of osteophytes and subcutaneous cysts, and subcutaneous sclerosis.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 will be 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. Six months after the injection, an MRI of the affected knee is taken again at the MRI imaging center of Rasoul Akram Hospital And changes are evaluated

Category

Treatment - Other

2

Description

Intervention group 2: The Group which treated by injection of platelet-rich plasma extracted double centrifuged. One week before the injection, an MRI of the patient's affected knee is performed at the MRI imaging center of Rasoul Akram Hospital. MRI of the knee will be performed by 1.5 T device with annular coil of the knee and in fat suppressed sequences of coronal, sagittal and axial PD and T1, T2 sagittal before and 6 months after treatment. MRI will be performed by two radiologists with experience in organ imaging who are unaware of the patient group and will examine and record cartilage thickness, joint space narrowing, the presence of osteophytes and subcutaneous cysts, and subcutaneous sclerosis. 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 will be 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. Six months after the injection, an MRI of the affected knee is taken again at the MRI imaging center of Rasoul Akram Hospital and changes are evaluated.

Category

Treatment - Other

3

Description

Control group: Therapeutic group with normal saline injection as a placebo group. One week before the injection, an MRI of the patient's affected knee is performed at the MRI imaging center of Rasoul Akram Hospital. MRI of the knee will be performed by 1.5 T device with annular coil of the knee and in fat suppressed sequences of coronal, sagittal and axial PD and T1, T2 sagittal before and 6 months after treatment. MRI will be performed by two radiologists with experience in organ imaging who are unaware of the patient group and will examine and record cartilage thickness, joint space narrowing, the presence of osteophytes and subcutaneous cysts, and subcutaneous sclerosis. 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. Six months after the injection, an MRI of the affected knee is taken again at the MRI imaging center of Rasoul Akram Hospital and changes are evaluated.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasool-e-Akram Hospital

Full name of responsible person
Mostafa Ghadamzadeh

Street address
Rasool-e-Akram Hospital; Niyayesh avenue; Sattarkhan street

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6653 9711

Email
ghadamzadeh.m@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mostafa Ghadamzadeh

Street address
Iran University of Medical sciences, south side of Hemmat highway

City
Tehran

Province
Tehran

Postal code
1458843337

Phone
+98 21 6651 9947

Email
Ghadamzadeh.m@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
Mostafa Ghadamzadeh

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Radiology

Street address
Rasool-e-Akram Hospital, Niyayesh avenue, Sattarkhan street

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6651 9947

Email
ghadamzadeh.m@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mostafa Ghadamzadeh

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Radiology

Street address
Rasool-e-Akram Hospital, Niyayesh avenue, Sattarkhan street

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6651 9947

Email
ghadamzadeh.m@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Seyed Amir Hossein Mohsenzadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiology
Street address
Rasool-e-Akram Hospital, Niyayesh avenue, Sattarkhan street
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6653 9711
Email
amir1442.m@yahoo.com

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
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
A reasonable request from an academic source will be responded within 10 working days.
From where data/document is obtainable
Mostafa Ghadamzadeh
What processes are involved for a request to access data/document
After sending an email by individuals or academic centers to the researcher, after confirming the data will be provided to them
Comments