Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

Comparative Study of The Effectiveness of The Injection of photo-activated Platelet Rich Plasma Compared with Platelet Rich Plasma on The Pain, Range of Motion and Function of Patients with Knee Osteoarthritis a double blind randomized control trial

Protocol summary

Study aim
Introducing an effective treatment method in improving the symptoms of knee osteoarthritis patients

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized with blocks of 4, phase 3 on 40 patients.

Settings and conduct
This study will be conducted in Hazrat Rasool Akram Hospital in Tehran. Patients with osteoarthritis of the knee will be selected based on the criteria for entering the study and after obtaining a written consent, they will be divided into two treatment groups: platelet-enriched plasma injection and platelet-enriched plasma injection activated by light radiation. The injection is done at an interval of one month. Patients are evaluated at months zero (first visit), one and six months. This research is double-blind, and the patient and the sports medicine specialist who performs the injection, the sports medicine resident who performs the evaluations before and after the intervention, and the analyst are unaware of which group the patients are placed in.

Participants/Inclusion and exclusion criteria
Entry criteria: Primary knee osteoarthritis grade 2 and 3 Age 50-75 years Constant knee pain Ability to walk independently for at least 30 meters Body mass index equal to or less than 35 Complete consent of the patient to participate in the research Balanced state of mind Non-entry conditions: History of knee intra-articular injection or recent physiotherapy and exercise therapy Suffering from neuromuscular diseases or malignant tumors Presence of acute traumatic injury History of previous surgery or injury in the lower limbs during the last year

Intervention groups
1-Platelet-enriched plasma injection as a control 2-Injection of plasma enriched with platelets activated by light radiation

Main outcome variables
Pain, range of motion and function of patients with knee osteoarthritis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140907019073N7**
Registration date: **2023-10-12, 1402/07/20**
Registration timing: **prospective**

Last update: **2023-10-12, 1402/07/20**
Update count: **0**

Registration date
2023-10-12, 1402/07/20

Registrant information

Name
Ali Mazaherinezhad

Name of organization / entity
IUMS

Country
Iran (Islamic Republic of)

Phone
+98 21 6435 2446

Email address
mazaherinezhad.a@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Study of The Effectiveness of The Injection of photo-activated Platelet Rich Plasma Compared with Platelet Rich Plasma on The Pain, Range of Motion and Function of Patients with Knee Osteoarthritis a double blind randomized control trial

Public title

Comparison of the effect of platelet-rich plasma injection activated by light radiation with platelet-rich plasma injection in the treatment of arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having primary knee osteoarthritis grade 2 and 3 according to the doctor's diagnosis and based on the Kellgren and Lawrence criteria (the presence of knee pain, morning dryness for less than 30 minutes, crypts during movement and radiological signs of osteoarthritis including joint space reduction, subchondral bone sclerosis and osteophyte formation in the knee) Age 50-75 years Having persistent knee pain for at least six months with a severity of at least 4 based on the VAS scale in activities such as going up and down the stairs, sitting for a long time and squatting Ability to walk independently for at least 30 meters Body mass index equal to or less than 35 Complete consent of the patient to participate in the research Balanced mental state

Exclusion criteria:

History of intra-articular injections in the knee during the last six months Having neuromuscular diseases Presence of acute traumatic injury in other ligaments and structures of the knee joint as confirmed by a specialist doctor History of previous surgery or injury in the knee and other joints of the lower limbs during the last year Presence of bone implants The presence of new fractures in the lower limbs during the last year Getting malignant tumors Participation in sports therapy and physiotherapy programs during the last three months

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of patients in treatment groups will be done randomly using blocks with 4 blocks in one of the treatment groups as follows: A: PRP B: PAPRP -Block1: AABB -Block2: ABAB -Block3: BBAA -Block 4: BABA

Blinding (investigator's opinion)

Double blinded

Blinding description

In this research, the following people will be compared to the treatment groups of blind patients: - The patients present in the research only know that they will be injected and will not know about the type of PRP used. Also, in this research, injection interventions will be performed under the supervision of a sports medicine specialist who does not know about the type of PRP and only injects the solution obtained with a glass syringe into the joint. - Assessor Clinician: Evaluations before and after interventions in the sports medicine assessment clinic are performed by the sports medicine resident who is not aware of the presence of patients in the groups. - Statistical Consultant and Analyzer: The analysis of the research data will be done by a statistical consultant who is not aware of the patient groups.

Placebo

Not 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

2023-10-07, 1402/07/15

Ethics committee reference number

IR.IUMS.FMD.REC.1402.297

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
Feeling knee pain by Visual Analogue Scale (VAS)
Timepoint
The time of follow-up of patients is zero months (first visit), one and six months.
Method of measurement
with the VAS questionnaire

2

Description
Knee function with WOMAC(Western Ontario and McMaster Universities Osteoarthritis Index) scale
Timepoint
The time of follow-up of patients is zero months (first visit), one and six months.
Method of measurement
with WOMAC questionnaire

Secondary outcomes

1

Description
Knee range of motion
Timepoint
The time of examination of patients is in zero months (initial visit), one and six months.
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
The time of examination of patients is in zero months (initial visit), one and six months.
Method of measurement
Stopwatch (seconds)

3

Description
Six Minute Walk test: The person's ability to walk for 6 minutes
Timepoint
The time of examination of patients is in zero months (initial visit), one and six months.
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
The time of examination of patients is in zero months (initial visit), one and six months.
Method of measurement
The number of steps taken

Intervention groups

1

Description
Control group: They are injected with platelet-rich plasma and this injection is repeated after one month. Preparation of solution and injection of PRP will be done in sports medicine clinic of Hazrat Rasool Akram (PBUH) hospital. Patients are asked to stop taking anticoagulants and aspirin (if used) a week before the injection with the permission of their doctor. To prepare PRP, kits (Arya Mabna Tashkis Corporation, RN: 312569, Rooyagen Kit) are used, which have a completely sterile pack. In order to prepare the injection solution, 35 cc of venous blood from the upper limb is taken from the patients by a 50 cc syringe, which has already drawn 5 cc of anticoagulant solution, and with the help of a blood transfusion adapter with an 18 G needle head and without any pressure on the piston, it is taken into the four A 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 his blood cells. All 4 tubes are filled in a balanced manner and placed inside the centrifuge and rotated at a speed of 1600 RPM for 10 minutes. placed and then the tubes are removed. Then the plasma separated by the first centrifuge in the tubes is drawn and poured into two other sterile 10 cc tubes inside the box that contain 0.6 cc of preservative with anti-platelet aggregation effect. Then it is put back into the machine and centrifuged at 3500RPM for 6 minutes. Then, after removing the upper plasma, 3 cc from the ends of each 2 tubes are drawn by a 5 cc syringe with a 14G needle and about 0.5 cc is separated to send 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 avoid weight bearing and heavy activities for 48 hours after injection. One of the most important ways to treat patients with knee osteoarthritis is the use of therapeutic exercises. A common exercise protocol will be prescribed for knee osteoarthritis patients participating in this study.
Category
Treatment - Drugs

2

Description

Intervention group: Under the injection of platelet-rich plasma that is irradiated with light before the injection for activation, and this injection is repeated after one month. In the PAPRP group, PRP is prepared like the first group and put into a sterile glass tube. transferred (the tubes of the kits used for PRP, including the kit we used in this study, are mainly made of compressed PVC and to prevent the absorption of light by these tubes and the possible interference with the effect of light on the activation of platelets for the radiation of solution light Sterile glass tubes are used) and the pre-injection glass tube is placed at a distance of 10 cm from the light source, which is a Bioptron PRO1 device with a wavelength of 3400-480 nm, for 5 minutes and then in the same way as before. It is ready to be injected. During the injection, the patient lies in a quiet environment and in the supine arch position, and the injected knee is placed in a 45 degree flexion position. The prepared PRP solution drawn into the syringe is slowly injected from the Infero Lateral area of the knee with a G14 needle head. After a 30-minute rest under the supervision of a sports medicine specialist, the patient is allowed to leave the clinic using a wheelchair. In case of pain, Yemar can take acetaminophen without codeine and is not allowed to take aspirin for 10 days. It is recommended that patients avoid weight bearing and heavy activities for 48 hours after injection. One of the most important ways to treat patients with knee osteoarthritis is the use of therapeutic exercises. A common exercise protocol will be prescribed for knee osteoarthritis patients participating in this study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasool Akram Hospital

Full name of responsible person
Ali Mazaherinezhad

Street address
Maziar Mansouri, StreetSattar Khan Street, Rasool Akram Hospital

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6435 2446

Email
mazaherinezhad@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Kazem musavizade

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

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 86701

Email
info@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

Street address
Hazrate-rasool-Hospital

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6435 2446
Fax
+98 21 6650 9108
Email
mazaherinezhad.a@iums.ac.ir

Person responsible for scientific 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
Street address
Hazrate-rasool-Hospital
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6435 2446
Fax
+98 21 6650 9108
Email
mazaherinezhad.a@iums.ac.ir

Person responsible for updating data

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
Street address
Hazrate-rasool-Hospital
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6435 2446
Fax
+98 21 6650 9108
Email
mazaherinezhad.a@iums.ac.ir

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
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