Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparative Study of The Effectiveness of The Injection of Platelet Rich Plasma with Using High Intensity Laser Therapy Compared with Platelet Rich Plasma and High Intensity Laser Therapy on The Pain, Range of Motion and Function of Patients with Knee Osteoarthritis a single blind randomized control trial

Protocol summary

Study aim

Comparative Study of The Effectiveness of The Injection of Platelet Rich Plasma with Using High Intensity Laser Therapy Compared with Platelet Rich Plasma and High Intensity Laser Therapy on The Pain, Range of Motion and Function of Patients with Knee Osteoarthritis a single blind randomized control trial

Design

parallel groups, single-blind, randomized, phase 3 on 60 patients, which will be used for randomization using blocks of six from the table of random numbers of R software.

Settings and conduct

Randomized single-blind clinical trial (participant and researcher) in Hazrat Rasool Akram Hospital, Tehran. Patients with osteoarthritis of the knee will be divided into three treatment groups by randomly assigning patients: platelet-enriched plasma (PRP) injection and high-power laser radiation together, and platelet-enriched plasma injection with placebo laser and high-power laser radiation alone.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.Grade 2 and 3 knee osteoarthritis for at least six months 2. Age 50-75 years. 3.Ability to walk independently for at least 30 meters. Exclusion criteria: 1.History of intra-articular injections in the knee during the last six months. 2.Acute traumatic injury in other ligaments and structures of the knee joint 3.Previous surgery or injury in the knee and other joints of the lower limbs during the last year.

Intervention groups

1-Platelet enriched plasma injection (PRP) and high intensity laser therapy (HILT) 2-Platelet-enriched plasma (PRP) and placebo laser injection 3- High intensity laser therapy (HILT)

Main outcome variables

Feeling knee pain by Visual Analogue Scale (VAS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140907019073N6**
Registration date: **2022-10-31, 1401/08/09**
Registration timing: **prospective**

Last update: **2022-10-31, 1401/08/09**
Update count: **0**

Registration date

2022-10-31, 1401/08/09

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

2022-11-02, 1401/08/11

Expected recruitment end date
2023-11-07, 1402/08/16
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 Platelet Rich Plasma with Using High Intensity Laser Therapy Compared with Platelet Rich Plasma and High Intensity Laser Therapy on The Pain, Range of Motion and Function of Patients with Knee Osteoarthritis a single blind randomized control trial

Public title
Comparison of the efficacy of platelet-enriched plasma injection and laser on knee arthrosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Grade 2 and 3 of primary knee osteoarthritis acording to KL criteria Age 50-75 year Persistent knee pain for at least 6 months with intensity more than 4 according to VAS in activity such as going up and down stair, long period of sitting and squatting Ability to walk independently for more than 30 m. BMI below 35 kg/m2 The patient has full consent to participate in the research. The patient should have 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
3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The block randomization method is used to assign people to the three study groups. For this purpose, the length of the block will be equal to 6 houses (two houses for each treatment). Group A: PRP injection and high-power HILT laser therapy, Group B: PRP injection and placebo laser group, Group C: HILT high-power laser therapy. To assign people to treatments, among the possible choices (number of 15 possible arrangements for blocks), 10 blocks are randomly selected and arranged in one order. Random numbers will be chosen to select 10 blocks out of 15 possible blocks, using R software with a placement-based method by a person who does not know the numbers of the blocks.Patients are assigned to treatments according to the proposed group in the field of selected blocks. This process continues until the end of the samples.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this research, -Assessor Clinician: Assessments before and after interventions in the sports medicine assessment 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: The analysis of the research data will be done by a statistical consultant who is not aware of the patient groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Medicine
Street address
Rasool-e-Akram Hospital, Niyayesh Ave, Sattarkhan St., Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1445613131
Approval date
2022-10-03, 1401/07/11
Ethics committee reference number
IR.IUMS.FMD.REC.1401.370

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
First Intervention group:First intervention group: Preparation of PRP solution and injection will be done in sports medicine clinic of Hazrat Rasool Akram Hospital. The patients of both groups 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. It is placed and then the tubes are removed.The plasma separated by the first round of centrifugation is drawn into the tubes and poured into two other sterile 10cc tubes inside the box which contain 0.6cc of anti-platelet agent, then put back into the machine and centrifuged at RPM 3500 and It is centrifuged for 6 minutes, then 3cc from the end of both tubes is drawn by a 5cc syringe with a G14 needle after removing the upper plasma.During the injection, the patient is lying supine in a quiet environment and the injected knee is in 45 degrees of flexion. The PRP solution prepared by any one of the methods drawn into the syringe is slowly injected into the knee from the Infero-Medial or Infero-Lateral area with a G21 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. The second injection will be performed 6 weeks later with the same protocol for these patients.The method of high-intensity laser therapy (HILT) for the first group that receives PRP platelet-enriched plasma injection and high-intensity laser therapy (HILT) will be as follows.The device used in the

research is Nd:YAG pulse laser (Physiomed Belgium company). The patient is placed in the Supine open arch position and his affected knee is placed in a 30 degree flexion position (in order to open the joint surface) (the knee angle will be controlled with a goniometer and a towel is placed under the patient's knee to maintain this position)), then the 6 cm applicator of the device is placed vertically in contact with the joint. Scanning of the joint longitudinal and transverse degrees beyond the internal and external joint line for a duration of 9 minutes with a power of 9 watts (Duty Cycle 70%) frequency 10 Hertz and energy density of 66j/cm2 will be done. Laser therapy will be performed for 6 weeks and 18 sessions (3 sessions per week) for the patients of this group.

Category

Treatment - Other

2

Description

Intervention group 2:Intervention group 2: The second group of platelet-enriched plasma (PRP) injection and placebo laser: The platelet-enriched plasma (PRP) injection group will receive a single PRP injection with the same protocol mentioned for the first group. For the placebo laser, with the same protocol mentioned, laser therapy is used for the first group, but with zero output power, which can be achieved by cutting the cable of the laser device.

Category

Treatment - Other

3

Description

Intervention group 3: Intervention group 3: The third group of high intensity laser therapy (HILT): for the group of high intensity laser therapy (HILT) with the same device and protocol mentioned for the first group, 12 sessions of laser therapy (3 sessions per week) for 4 weeks. will be done.

Category

Treatment - Other

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.

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 2446

Email

mazaheri.a@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Ali mazaherinezhad

Street address

Niayesh Ave., Sattarkhan St. tehran

City

Tehran

Province

Tehran

Postal code

1458843337

Phone

+98 21 6435 2446

Email

mazaherinezhad@gmail.com

Grant name

Grant code / Reference number

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

No

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
1449614535
Phone
+98 21 6435 2446
Fax
+98 21 6650 9108
Email
mazaherinezhad@gmail.com

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
1449614535
Phone
+98 21 6435 2446
Fax
+98 21 6650 9108
Email
mazaherinezhad@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Marzieh Fazlinejad
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Sport Medicine
Street address
Rasool-e-Akram Hospital, Niayesh St, Sattarkhan Boulevard
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 6653 7308
Email
m.fazlinezhad@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available