

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effectiveness of platelet-enriched plasma along with vitamin D and platelet-enriched plasma without vitamin D in improving function and reducing pain in knee osteoarthritis patients

Protocol summary

Study aim

Investigating the effect of platelet-enriched plasma injection with vitamin D on pain sensation and functional status of the knee

Design

This study will be conducted with a control group, with parallel groups, three blinded groups and using block randomization method on 100 patients.

Settings and conduct

This study will be conducted in patients with osteoarthritis referred to Shahid Madani Hospital in Karaj who are eligible to enter the study. The study is triple blind and the patients, the outcome evaluator and the person administering the injection will not be aware of the patients' belonging to the treatment groups

Participants/Inclusion and exclusion criteria

Having informed consent; Suffering from osteoarthritis based on the criteria of the American Rheumatology Association; Receiving non-invasive treatments for at least 6 months; Having a body mass index below 30y No history of fracture or previous surgery on the studied joint; Absence of diagnosis of secondary osteoarthritis; No history of drug sensitivity.

Intervention groups

In the intervention group, first, 20 ml of blood is taken from the patient and centrifuged for 15 minutes at 1600 rpm to separate the erythrocytes and then 7 minutes at 2800 rpm to concentrate the platelets, then 300,000 IU of vitamin D solution is added to it. 8 minutes before the injection, the skin of the injection site is anesthetized by injecting 2 ml of 1% lidocaine. 3 ml of the prepared solution is drawn into a syringe and injected into the knee joint. All the above cases are also done for the comparison group, with the difference that in this group, the injected solution does not contain vitamin D

Main outcome variables

Feeling pain in the knee joint; the functional state of the

knee joint

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230224057514N1**

Registration date: **2023-03-15, 1401/12/24**

Registration timing: **prospective**

Last update: **2023-03-15, 1401/12/24**

Update count: **0**

Registration date

2023-03-15, 1401/12/24

Registrant information

Name

Amir hossein Haghshenas

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3442 5029

Email address

yousefkhani13633@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of platelet-enriched plasma along with vitamin D and platelet-enriched plasma without vitamin D in improving function and reducing pain in knee osteoarthritis patients

Public title

Vitamin D in knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having informed consent Suffering from osteoarthritis based on the criteria of the American Rheumatology Association Receiving non-invasive treatments for at least 6 months Having a body mass index below 30

Exclusion criteria:

History of fracture or previous surgery on the studied joint Diagnosis of secondary osteoarthritis History of drug sensitivity

AgeFrom **50 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample sizeTarget sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description

The block randomization method will be used for randomization. The length of the block is considered to be 4 for each of the treatment groups, that is, each block will include two people from the intervention group and two people from the comparison group. We denote the intervention group with the letter A and the people of the comparison group with the letter B. In this case, we will have 6 combinations of four in the form of (AA,BB), (AB,BA), (BA,BA), (BA,BA), (BB,AA), and (AB,BA). In the Excel software, these blocks are sorted from 1 to 6, and then with the help of this software, one of these blocks is randomly selected, and based on the sequence of letters A and B in the selected block, the eligible people refer to and Admissions will be assigned to treatment or comparison groups. This random process of selecting blocks and assigning people to intervention and comparison groups will continue until the desired sample size is reached.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is designed in a triple-blind manner, so that the injector, the outcome assessor and the patient are

not aware of the status of assigning people to the study groups. For the study subjects, before the random allocation, it is explained how the work process is and they may receive one of the two treatments randomly, and the drug used for the subjects is not known in advance. On the other hand, the injection of vitamin D and PRP in the intervention group is done in the same syringe as in the PRP only (comparison) group, so the patient will be unaware of which group he is in. The injecting person will also be unaware of the patients' belonging to the treatment groups, because the sampling and preparation of the injectable substance is done by another person, and after entering the study, people will be anonymously and with a code to the injecting agent. they are introduced. Also, the outcome evaluator will not know about the status of assigning people to the study groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Alborz University of Medical Sciences

Street address

Vice President of Research and Technology of Alborz University of Medical Sciences, Safarian St, Golshahr, Karaj

City

Karaj

Province

Alborz

Postal code

3198764653

Approval date

2023-02-19, 1401/11/30

Ethics committee reference number

IR.ABZUMS.REC.1401.316

Health conditions studied**1****Description of health condition studied**

Osteoarthritis of the knee joint

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Knee joint pain

Timepoint

Pain measurement will be done at the beginning of the study, the first week, the first month, the second month and the sixth month after the treatment.

Method of measurement

Vas score index

2

Description

Functional status of the knee joint

Timepoint

The functional condition of the knee joint will be examined at the beginning of the study, the first week, the first month, the second month and the sixth month after the treatment.

Method of measurement

WOMAC score index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, first, 20 ml of blood is taken from the patient and centrifuged for 15 minutes at 1600 rpm to separate the erythrocytes and then 7 minutes at 2800 rpm to concentrate the platelets, then 300,000 IU of vitamin D solution is added to it. 8 minutes before the injection, the skin of the injection site is anesthetized by injecting 2 ml of 1% lidocaine. 3 ml of the prepared solution is drawn into a syringe and injected into the knee joint.

Category

Treatment - Drugs

2

Description

Control group: All the above cases are also done for the comparison group, with the difference that in this group, the injected solution does not contain vitamin D

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital

Full name of responsible person

Amirhossein Haghshenas

Street address

Shahid madani hospital, Mahan blvd, Jahanshahr, Karaj

City

Karaj

Province

Alborz

Postal code

3143744693

Phone

+98 26 3442 7001

Email

face.off1990amir@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Razieh Lotfi

Street address

Vice President of Research and Technology of Alborz University of Medical Sciences, Safarian St, Golshahr, Karaj

City

Karaj

Province

Alborz

Postal code

3198764653

Phone

+98 26 3464 3705

Email

research@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Amirhossein Haghshenas

Position

Orthopedic resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Phone

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face.off1990amir@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Amirhossein Haghshenas

Position

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Email

face.off1990amir@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Amirhossein Haghshenas

Position

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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

Participants Data File, Study Protocol, Statistical Analysis Map, Consent Form and Clinical Study Report will be shared after completion of the study. Participants' data file is not identifiable by others

When the data will become available and for how long

The data of this study will be shared one month after printing the results and will be available for one year

To whom data/document is available

All researchers interested in research in this study can access data

Under which criteria data/document could be used

1. People who request access to data must be committed to the intellectual rights of researchers. 2. Avoid data manipulation and consequently unrealistic analysis.

From where data/document is obtainable

Researchers interested in access to data in this study can refer to the clinical research unit of Shahid Madani Hospital

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

Researchers interested in access to data in this study can refer to the Shahid Madani Hospital Clinical Research Development Unit and submit their official request to access data. After making the necessary reviews and obligations, the data will be made available to them.

Comments