

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

The effects of platelet lysate therapy and platelet-rich plasma on chronic knee osteoarthritis

Protocol summary

Study aim

Effect of platelet lysate (PL) and platelet-rich plasma (PRP) on chronic knee osteoarthritis (OA)

Design

25 patients were selected based on radiologic findings with a period of 3 months symptoms of knee OA and PL was used for left knee and PRP was used for right knee. For the preparation of PL, 20 ml of blood from the upper cubital vein will be taken and, after production of PRP and, in order to produce PL, it is frozen at -80 ° C for 60 minutes, and then at 37°C Melt for 15 minutes. Then, centrifuge the platelets and WBC to remove the membranes and filter with 0.22 micrometers.

Settings and conduct

The following items for the patients who are most relevant, recorded: 1) Pain by visual analog scale (VAS) 2) Knee function by the WOMAC 3)The thickness of the knee cartilage using MRI After PL and PRP quality control, patients will be referred to the Rehabilitation and Physical Medicine Department of the Shahid Madani Hospital for the injection of PL and PRP in the knee. An injection of PL and PRP into patients will be done by supralateral method, in which the patient will rest on the back and the knee will almost completely open. A second injection is repeated at intervals of 21 days. Then, in order to evaluate the effect of PL and PRP on patients in the intervals of 1and 6 months after the first injection, the cases mentioned above will be recorded.

Participants/Inclusion and exclusion criteria

A total of 25 patients were selected based on radiologic findings with a period of three-month symptoms of knee OA.

Intervention groups

Treatment of left knee with PL Treatment of right knee with PRP

Main outcome variables

1- Determining knee pain by VAS in all phases of clinical trial 2-Determination of knee function by WOMAC in all phases of clinical trial 3-Determine the range of knee

motion by manual jointometry in all phases of the trial 4-Measuring Growth Factors in PL and PRP

General information

Reason for update

In this study, platelet-rich plasma was also used. The sample size was 25 people.1 and 6-month follow-up examination was performed. KOOS questionnaire removed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20160422027520N10**
Registration date: **2019-02-27, 1397/12/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-08, 1399/11/20**

Update count: **1**

Registration date

2019-02-27, 1397/12/08

Registrant information

Name

Mehdi Yousefi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-09, 1397/11/20

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of platelet lysate therapy and platelet-rich plasma on chronic knee osteoarthritis

Public title

Treatment of chronic knee osteoarthritis with platelet lysis and platelet-rich plasma

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Men and women between the ages of 18 and 75 with OA diagnosis based on the American College of Rheumatology Analog scale of knee pain (VAS) equal to or greater than 2.5 People with at least 4 months of history of pain or swelling in one or both knees Radiological classification scale Kellgren-Lawrence 1 or 2 The availability of individual during the study period BMI Between 20 and 35

Exclusion criteria:

People under the age of 18 and over 75 years Pregnant women or women who are breastfeeding People with malignancy, People with severe heart disease, uncontrolled diabetes mellitus, rheumatoid arthritis, hemorrhagic diseases, history of anemia, arthritis, fibromyalgia and chronic fatigue syndrome Those linked to acetaminophen or Vicodin or a history of drug misuse History of cortisone injections in the last 6 weeks The use of non-steroidal anti-inflammatory drugs 1 week ago Having hemoglobin less than 11 g / dl and platelet count less than 150000 / μ The use of inhibitors of platelet aggregation and anti-coagulation such as heparin History of knee surgery in the last 3 months Extraordinary deformation (varus $>5^\circ$, valgus $>5^\circ$)

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences , Daneshghah st, Tabriz,

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Tabriz

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East Azarbaijan

Postal code

5166614766

Approval date

2019-02-04, 1397/11/15

Ethics committee reference number

IR.TBZMED.REC.1397.923

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

Knee Osteoarthritis

ICD-10 code

M15.4

ICD-10 code description

Erosive (osteo)arthritis

Primary outcomes**1****Description**

Determining knee pain by VAS in all phases of clinical trial

Timepoint

1 and 6 months after the first injection

Method of measurement

Questionnaire (Visual Analogue Scale)

2**Description**

Determination of knee function by Western Ontario and McMaster Universities Osteoarthritis Index in all phases of clinical trial

Timepoint

1 and 6 months after the first injection

Method of measurement

Questionnaire (Western Ontario and McMaster

Universities Osteoarthritis Index)

3

Description

Determine the range of knee motion by manual jointometry in all phases of clinical trial

Timepoint

1 and 6 months after the first injection

Method of measurement

Range of motion (Degree)

4

Description

Measurement of growth factors in platelet lysate and Platelet-rich plasma

Timepoint

1 and 6 months after the first injection

Method of measurement

Elisa

Secondary outcomes

1

Description

Determine the thickness of the knee cartilage

Timepoint

6 months after the first injection

Method of measurement

MRI

Intervention groups

1

Description

Intervention group: Patients with knee arthritis receiving platelet lysate and platelet-rich plasma

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital, Tabriz

Full name of responsible person

Mehdi Yousefi, Ph.D Of Medical Immunology

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Department of Immunology, Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran

Full name of responsible person

Mehdi Yousefi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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