Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 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 joiniometry 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

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

Country

Iran (Islamic Republic of)

Phone

+98 41 3336 4665

Email address

yousefime@tbzmed.ac.ir

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 / mμ 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°, valgus >5°)
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,
City
Tabriz
Province
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 joiniometry 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
Street address
Shahid Madani Hospital, Golbad Avenue, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3335 7767
Email
mehdi_yusefi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Samie
Street address
Tabriz University of Medical Sciences, Golgasht Avenue, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3335 5921
Email
mehdi_yusefi@yahoo.com
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
Immunology
Street address
Tabriz University of Medical Sciences, Golgasht Avenue,Tabriz, Iran
City

Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3336 4665
Fax
+98 41 3336 4665
Email
yousefime@tbzmed.ac.ir

Person responsible for scientific 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
Immunology
Street address
Tabriz University of Medical Sciences, Golgasht Avenue,Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3336 4665
Fax
+98 41 3336 4665
Email
yousefime@tbzmed.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mehdi Yousefi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Immunology
Street address
Tabriz University of Medical Sciences, Golgasht Avenue,Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3336 4665
Fax
+98 41 3336 4665
Email
yousefime@tbzmed.ac.ir

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