Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effects of PRP with reduced Leukocyte content therapy on chronic knee osteoarthritis

Protocol summary

Study aim
The effects of PRP with reduced Leukocyte content therapy on chronic knee osteoarthritis

Design
This study is single-blind, phase 2 clinical trials on 15 patients based on inclusion and exclusion criteria, the study procedure will be explained to patients, and informed consent will be obtained before the study. One knee will be randomly selected for leukocyte-rich PRP injection and another knee will be injected using PRP with reduced Leukocyte content.

Settings and conduct
Initially, the following items will be recorded for the patients who meet the inclusion criteria: Pain by VAS, Knee function by WOMAC, Knee function by KOOS, Flexion range of motion. After PRP preparation, patients will be referred to the Rehabilitation Department of the Shahid Madani Hospital. PRP injection will be given to patients supralaterally. The injection will be repeated twice with a 21 days apart. Then, the effect of PRP on patients will be evaluated in the intervals of 1, 3 and 6 months after the first injection.

Participants/Inclusion and exclusion criteria
Radiologic findings with a period of three-month symptoms of knee osteoarthritis in both of knees. No history of knee surgery, blood disorders and confounders in the study results and no extraordinary deformation

Intervention groups
PRP with reduced Leukocyte content Treatment group, Control group: treatment with Leukocyte-rich PRP.

Main outcome variables
1- Determining knee pain by VAS in all phases of clinical trial 2-Determination of knee function by WOMAC and KOOS in all phases of clinical trial 3-Determine the range of knee motion by manual joiniometry in all phases of the trial

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160422027520N14**
Registration date: **2019-08-24, 1398/06/02**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-30, 1398/10/09**
Update count: **1**

Registration date
2019-08-24, 1398/06/02

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)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-23, 1398/06/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of PRP with reduced Leukocyte content therapy on chronic knee osteoarthritis

Public title
Treatment of chronic knee osteoarthritis with PRP with reduced Leukocyte content

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 People with acetaminophen or vicodin addiction 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
2

Groups that have been masked

- Participant

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
The study participant will be unaware of his placement in the study group (PRP with reduced Leukocyte content or Leukocyte-Rich PRP).

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
2019-07-29, 1398/05/07

Ethics committee reference number
IR.TBZMED.REC.1398.472

Health conditions studied

1

Description of health condition studied
Osteoarthritis

ICD-10 code
M15.4

ICD-10 code description
Erosive (osteo)arthritis

Primary outcomes

1

Description
Determining knee pain

Timepoint
Before injection and 1, 3 and 6 months after the first injection

Method of measurement
Questionnaire (VAS)

2

Description
Determination of knee function

Timepoint
Before injection and 1, 3 and 6 months after the first injection

Method of measurement
Questionnaire (WOMAC), Questionnaire (KOOS)

3

Description

Determine the range of knee motion

Timepoint

Before injection and 1, 3 and 6 months after the first injection

Method of measurement

Manual joiniometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group of patients, 10 ml of blood will be taken by PRP-specific syringe manufactured by Pishtaz Teb Zaman CO. and according to kit protocol, we will separate the PRP with reduced Leukocyte content. The PRP will then be injected by a physician into one of the two knees of the patient with knee osteoarthritis. The PRP injection volume will be 2 cc.The injection will be repeated twice with a 21 days apart.

Category

Treatment - Other

2

Description

Control group: Leukocyte-rich PRP will be Prepared and by the physician will be injected into another patient's knee. The PRP injection volume will be 2 cc. The injection will be repeated twice with a 21 days apart.

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

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5166614766

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Email

mehdi_yusefi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pishtaz Teb Zaman CO.

Full name of responsible person

Behrooz Hajeian Tehrani

Street address

Golha, Pishtaz Teb Zaman CO.

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Province

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Postal code

1494734463

Phone

+98 21 4219 7000

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

Pishtaz Teb Zaman CO.

Proportion provided by this source

100

Public or private sector

Private

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

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Yousefi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Person responsible for updating data

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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