Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

The effects of platelet lysate therapy on knee

Protocol summary

Study aim
Evaluation of the effectiveness of platelet lysate on the recovery of knee meniscus
Design
This study is clinical trial with control group, with parallel group, single-blind, Non-randomized to Intervention and control group, phase 2 on 15 patients.
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 platelet lysate (PL) and platelet rich plasma (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 PL and PRP on patients will be evaluated in the intervals of 1, 3, 6 and 12 months after the first injection.
Participants/Inclusion and exclusion criteria
Radiologic findings with a period of three-month symptoms of knee meniscus in both of knees. No history of knee surgery, blood disorders and confounders in the study results and no extraordinary deformation
Intervention groups
Treatment group: Platelet lysate. Control group: Platelet rich plasma.
Main outcome variables
knee pain; knee function;; range of knee motion

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20160422027520N18**
Registration date: **2020-08-25, 1399/06/04**
Registration timing: **prospective**

Last update: **2020-08-25, 1399/06/04**
Update count: **0**
Registration date
2020-08-25, 1399/06/04

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-09-05, 1399/06/15
Expected recruitment end date
2020-12-05, 1399/09/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of platelet lysate therapy on knee

Public title
Treatment of knee meniscus with platelet lysis
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 6 months of history of meniscus in both knees Radiological classification scale Kellgren-Lawrence 1 or 2 The availability of individual during the study period BMI Between 20 and 35 Positive joint line tenderness test Positive thessaly test

Exclusion criteria:

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

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 (Platelet rich plasma or platelet lysate). After obtaining informed consent and blood sampling from patients, platelet rich plasma (PRP) and platelet lysate (PL) are prepared. The patient does not know to which knee PRP or PL is injected, and only researchers and physicians know the type of blood product being injected.

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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Approval date

2020-08-10, 1399/05/20

Ethics committee reference number

IR.TBZMED.REC.1399.502

Health conditions studied

1

Description of health condition studied

Knee meniscus

ICD-10 code

M23.005

ICD-10 code description

Cystic meniscus, unspecified medial meniscus, unspecified knee

Primary outcomes

1

Description

Determining knee pain by VAS in all phases of clinical trial

Timepoint

1, 3, 6 and 12 months after the first injection

Method of measurement

Questionnaire (VAS)

2

Description

Determination of knee function by WOMAC and KOOS in all phases of clinical trial

Timepoint

1, 3, 6 and 12 months after the first injection

Method of measurement

Questionnaire (WOMAC), Questionnaire (KOOS)

3

Description

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

Timepoint

1, 3, 6 and 12 months after the first injection

Method of measurement

Range of motion (Degree)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Fifteen patients with knee meniscus receive platelet lysate (PL) as the intervention group. Initially, receive informed consent from the patients and the following will be recorded for these patients who meet the inclusion criteria: 1) Pain by VAS 2) Knee function by WOMAC 3) Knee function by KOOS 4) Flexion range of motion (ROM). In this group of patients, 10 ml of blood was taken and will be used for PL preparation. The PL is then injected by a physician into one of the two knees of the patient with knee meniscus. The injection volume of PL is 2 cc.Repeat injections twice again 21 days apart.Then, in order to evaluate the effect of PL on patients in the intervals and Compare it with another patient's knees who received platelet rich plasma, 1, 3, 6 and 12 months after the first injection, 1) Pain by VAS 2) Knee function by WOMAC 3) Knee function by KOOS 4) Flexion range of motion (ROM) will be recorded.

Category

Treatment - Other

2

Description

Control group: Fifteen patients with knee meniscus receive platelet rich plasma (PRP) as the intervention group. Initially, receive informed consent from the patients and the following will be recorded for these patients who meet the inclusion criteria: 1) Pain by VAS 2) Knee function by WOMAC 3) Knee function by KOOS 4) Flexion range of motion (ROM). Then 10 ml of blood was taken of patients and will be used for PRP preparation. The PRP is then injected by a physician into one of the two knees of the patient with knee meniscus. The injection volume of PRP is 2 cc.Repeat injections twice again 21 days apart.Then, in order to evaluate the effect of PRP on patients in the intervals and Compare it with another patient's knees who received platelet lysate, 1, 3, 6 and 12 months after the first injection, 1) Pain by VAS 2) Knee function by WOMAC 3) Knee function by KOOS 4) Flexion range of motion (ROM) will be recorded.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital, Tabriz

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Yousefi

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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