

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Evaluation and comparison of the effect of platelet-rich plasma therapy and arthroscopic surgery on anterior cruciate ligament ligament rupture

Protocol summary

Study aim

Evaluation and comparison of the effect of platelet-rich plasma therapy and arthroscopic surgery on anterior cruciate ligament ligament rupture

Design

Clinical trial with control group with parallel groups, phase 2-3 on 100 patients

Settings and conduct

This study will be performed in 501 Army Hospital in Tehran. 100 patients will be divided into two groups of surgical treatment and PRP. Patients' pain and function will be measured and compared one year after treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 70 years, detection of anterior cruciate ligament rupture by imaging, referring to the 501 Artesh Hospital, having the written informed consent to participate in the study No-entry criteria: Willingness to have surgery, lack of access to the patient

Intervention groups

Intervention group 1: Patients in this group will be treated for anterior cruciate tendon repair by arthroscopy and tendon graft. Intervention group 2: Patients in this group will be treated with PRP. PRP treatment involves taking 40 cc of venous blood from patients in which blood samples are centrifuged and the platelet section is removed. After disinfecting the injection site, PRPs are injected into the affected joint and patients will then be treated with a hinge-knee brace.

Main outcome variables

Pain and knee function.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200217046523N18**

Registration date: **2021-10-22, 1400/07/30**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-22, 1400/07/30**

Update count: **0**

Registration date

2021-10-22, 1400/07/30

Registrant information

Name

Aryan Rafiee Zadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3837 1582

Email address

rafieezadeh.a@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-22, 1400/07/30

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the effect of platelet-rich plasma therapy and arthroscopic surgery on anterior cruciate ligament ligament rupture

Public title

Platelet-rich plasma and arthroscopic surgery for anterior cruciate ligament ligament rupture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 70 years Detection of anterior cruciate ligament rupture by imaging Referring to the 501 Artesh Hospital Having the written informed consent to participate in the study

Exclusion criteria:

Willingness to have surgery Lack of access to the patient

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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 the Arteshof the of the Islamic Republic of Iran University of Medical Sciences

Street address

Artesh University of Medical Sciences, Etemadzadeh St., West Fatemi St., Tehran

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2021-03-01, 1399/12/11

Ethics committee reference number

IR.AJAUMS.REC.1399.258

Health conditions studied

1

Description of health condition studied

Anterior cruciate ligament rupture

ICD-10 code

S83. 512A

ICD-10 code description

Sprain of anterior cruciate ligament of left knee

Primary outcomes

1

Description

Pain

Timepoint

Before and one year after interventions

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Knee function

Timepoint

Before and one year after interventions

Method of measurement

Score Knee Oxford

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients in this group will be treated for anterior cruciate tendon repair by arthroscopy and tendon graft.

Category

Treatment - Surgery

2

Description

Intervention group 2: Patients in this group will be treated with PRP. PRP treatment involves taking 40 cc of venous blood from patients in which blood samples are centrifuged and the platelet section is removed. After disinfecting the injection site, PRPs are injected into the affected joint and patients will then be treated with a hinge-knee brace.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

501 Arthesh hospital

Full name of responsible person

Shamim Fatah

Street address

501 Arthesh hospital, End of Oshan Boulevard, Arthesh Highway, Tehran.

City

Tehran

Province

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Postal code

1956944141

Phone

+98 21 2248 1806

Email

sepehr.eslami2004@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Mojtaba Yousefi Zeshk

Street address

Artesh University of Medical Sciences, Etemadzadeh St., West Fatemi St., Tehran

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1411718541

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Email

Yousefi.Zeshk@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Shamim Fatah

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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501 Arthesh hospital, End of Oshan Boulevard, Arthesh Highway, Tehran.

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Website of the Research Committee of Artesh University of Medical Sciences

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

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments