

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Evaluation of the effect of platelet rich plasma on outcomes after arthroscopic microfracture surgery in osteochondral lesions of talus

Protocol summary

Study aim

to evaluate the effect of Platelet Rich Plasma (PRP) on post-op patient improvement and tissue healing

Design

this study is done on patients who underwent arthroscopic surgery. the patients were split into PRP and control groups using a random number generator. the PRP group received 2 doses of PRP and both groups were evaluated using scoring systems.

Settings and conduct

this study is done in the shohada-e-tajrish hospital in Tehran, Iran.

Participants/Inclusion and exclusion criteria

inclusion: patients undergoing arthroscopic surgery of talus patients over 18 years old exclusion: patients who did not consent to the study patients with previous ankle surgery history patients with previous ankle fracture history patients with foot and ankle deformities patients who underwent other modalities such as mosaicplasty or grafting coagulopathy patients patients using anticoagulants patients who exited the study and did not want to continue

Intervention groups

in the PRP arm, after 1 week of surgery 2 doses of PRP was injected with an interval of 1 week. the 22 gauge needle was injected medial to anterior tibialis through the joint line into the joint space and PRP was injected. the control group underwent the surgery alone and were followed up

Main outcome variables

patients were evaluated using AOFAS and VAS scoring systems

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230227057547N1**

Registration date: **2023-05-12, 1402/02/22**

Registration timing: **retrospective**

Last update: **2023-05-12, 1402/02/22**

Update count: **0**

Registration date

2023-05-12, 1402/02/22

Registrant information

Name

Hamed Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2268 9199

Email address

masaro1982@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

2020-03-20, 1399/01/01

Actual recruitment end date

2021-03-21, 1400/01/01

Trial completion date

empty

Scientific title

Evaluation of the effect of platelet rich plasma on outcomes after arthroscopic microfracture surgery in osteochondral lesions of talus

Public title

effect of post surgery platelet rich plasma on

osteochondral lesions of talus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients undergoing arthroscopic surgery for osteochondral talus lesions patients older than 18 years

Exclusion criteria:

patients who did not consent patients with previous ankle surgery patients with previous ankle fracture patients with foot deformities patients using other treatments (graft etc) coagulopathy patients patients using anticoagulants patients who left the study or did not continue

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

we used a random number generator software to randomly assign the patients into two groups of PRP and control while taking into consideration the demographic features and the VAS and AOFAS scores.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of shahid beheshti university of medical sciences

Street address

shahid beheshti university of medical sciences, koodakyar street, velenjak, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-03-21, 1401/01/01

Ethics committee reference number

IR.SBMU.MSP.REC.1401.377

Health conditions studied

1

Description of health condition studied

osteochondral lesion of the talus

ICD-10 code

M93.9

ICD-10 code description

Osteochondropathy, unspecified

Primary outcomes

1

Description

AOFAS score

Timepoint

12 months after injection

Method of measurement

history and physical examination

2

Description

VAS (Visual Analog Scale) score

Timepoint

12 months after injection

Method of measurement

history and physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: after surgery the patient receives two injections of PRP

Category

Treatment - Drugs

2

Description

Control group: only undergo surgery/ no placebo given/ no prp injection recieved

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada-e-Tajrish hospital, Tehran

Full name of responsible person

Hamed Nazari

Street address

Shohada-e-Tajrish hospital, Tajrish square, Tehran, Iran

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1989934148

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Pr_shohada@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hamed Nazari

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amir Sabaghzadeh Irani

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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shohada tajrish hospital, Tajrish square, Tehran, Iran

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Position

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Person responsible for updating data

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Latest degree

Specialist

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

anonymized patient data will be made available, age and sex data will also be available

When the data will become available and for how long

the data will become available 1 year after publication of results

To whom data/document is available

the data will be only available to people working in academic institutions

Under which criteria data/document could be used

any analysis or use of the data for research purposes is only allowed with written permission from the orthopedics department of shohada e tajrish hospital

From where data/document is obtainable

shohada e tajrish hospital, tajrish square, tehran , Iran
Dr. Amir Sabaghzade Irani (orthopedics professor)

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

one should contact Dr. Sabaghzadeh and seek permission to be able to obtain data from the documentary of shohada e tajrish hospital and shahid beheshti university of medical sciences if necessary

Comments