Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Sep 2026

Therapeutic impact of Adipose-derived Stromal Vascular Fraction And Platelet-rich plasma on non-operative treatment of osteochondral lesions of the talus: A Randomized Controlled Trial

Protocol summary

Study aim
Comparing the effect of stromal vascular fraction and Platelet-rich plasma on talus osteochondritis

Design
A controlled, two-parallel, randomized, unblinded phase 2 clinical trial on 40 patients. The NIH site was used for randomization

Settings and conduct
Patients are enrolled in the study at Akhtar Hospital and undergo diagnostic and therapeutic interventions at Shahada Tajrish Hospital, which include MRI and CT scan. Then the questionnaires are completed and they are subjected to intra-articular injection in the same center. Blinding is not possible due to the different method in the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria in the study: The symptoms have been continuous for at least 3 months, and has not responded to conservative treatment Exclusion criteria from the study: Surgery or intra-articular injection

Intervention groups
The intervention group of talus osteochondritis patients receiving svf(stromal vascular fraction) The intervention group of talus osteochondritis patients receiving PRP (Platelet-rich plasma)

Main outcome variables
American Orthopedic Foot and Ankle Society scores, visual analog scale, Ankle Osteoarthritis Scale, lesion diameter and lesion grade

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231212060345N1**
Registration date: **2024-02-04, 1402/11/15**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-04, 1402/11/15**
Update count: **0**

Registration date
2024-02-04, 1402/11/15

Registrant information
Name
Sina Hajiaghajani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 2610 6712
Email address
sinaaghajani1379@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-05, 1402/10/15

Expected recruitment end date
2025-01-04, 1403/10/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Therapeutic impact of Adipose-derived Stromal Vascular Fraction And Platelet-rich plasma on non-operative treatment of osteochondral lesions of the talus: A Randomized Controlled Trial

Public title

The effect of vascular stromal cells and platelet-rich plasma in the treatment of osteochondral lesions of the talus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The symptoms have been continuous for at least 3 months and have not responded to conservative treatment age 18-70 years Patients with grade I, II Bernadet and Harry classification lesions CT SCAN and MRI confirm the diagnosis and no other pathology is involved The patient has the ability to understand the explanations and registers her verbal and written wishes in the informed consent form

Exclusion criteria:

presence of inflammatory arthritis such as rheumatoid arthritis, other systemic diseases such as diabetes and systemic inflammatory diseases; Systemic infection History of cardiovascular disease such as previous stroke or heart failure or coagulation problem such as disturbed PT, PTT, INR Any surgery or intra-articular injection Drug users or alcoholics Pregnancy or breastfeeding Severe weight loss in such a way that liposuction is not possible. Abdominal hernia The presence of loose bodies, osteoarthritic changes, impingement spurs, or other pathology

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is simple, the randomization is individual, there is no stratified randomization, randomization with the NIH site tool, and the final Excel is prepared for randomization. Is. After entering the study according to the conditions mainly mentioned above, it is determined what intervention is performed for each patient based on a predetermined chain in Excel. For example, row 1 T is equivalent to the intervention group or row 2 C is equivalent to the control group. The patients are chained according to the order of referral, the first patient in the first row, the second patient in the second row, and so on

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

Working Group/Committee of Research Ethics of Dermatology Research Center - Shahid Beheshti Universi

Street address

Tehran - Quds town (west) - between South Flamak and Zarafshan, Simai Iran St. - Central Headquarters of Ministry of Health, Treatment and Medical Education, Block A, 13th floor

City

tehran

Province

Tehran

Postal code

1333635445

Approval date

2023-11-01, 1402/08/10

Ethics committee reference number

IR.SBMU.SRC.REC.1402.019

Health conditions studied

1

Description of health condition studied

talus osteochondral lesions- talus osteochondritis dissecans

ICD-10 code

M93.27

ICD-10 code description

Osteochondritis dissecans of ankle and joints of foot

Primary outcomes

1

Description

diameter of Lesion

Timepoint

before entering the study - six months later

Method of measurement

CT scan

Secondary outcomes

1

Description

function of ankle

Timepoint

before entering the study - one month later - three months later - six months later

Method of measurement

American Orthopedic Foot and Ankle Society questionnaire

2

Description
pain
Timepoint
before entering the study - one month later - three months later - six months later
Method of measurement
visual analog scale

3

Description
osteoarthritis changes
Timepoint
before entering the study - one month later - three months later - six months later
Method of measurement
Ankle osteoarthritis scale questionnaire

4

Description
Lesion grade
Timepoint
before entering the study - six months later
Method of measurement
CT scan - Berndet and harty classification

Intervention groups

1

Description
Intervention group: intra-articular injection of vascular stromal cells taken from fat, necessary equipment, svf extraction kit-syringe, SVF preparation: about 100 mL of adipose tissue is taken sterilely through liposuction of the abdomen. The obtained fat will be emulsified by passing through 2.4 mm, 1.2 mm filters and finally a 400 and 600 micrometer filter (25-30 passes). In order to separate free fatty acids, these nanofats are centrifuged (for 2 minutes at 1200 rpm) and the separated fatty acids will be discarded. The number of cells in the remaining substance will be counted under the microscope. The obtained nanofat is prepared for injection into the joint. The injection volume is 4-5 cc. The quantity and viability of the cells is done through direct observation under the neobar slide. After the injection, the patient must not apply weight for 24 hours The leg should be restrained (walk with a cane) and only paracetamol is allowed to be used for pain control. After a week, the patients will be contacted and questions will be asked about possible side effects.
Category
Treatment - Other

2

Description
Control group: Intervention group: intra-articular injection of platelet-rich plasma taken from peripheral blood, necessary equipment for PRP extraction kit-syringe, first blood is taken from a peripheral vein, then PRP is extracted from it with a centrifuge and injected for one time after injecting the patient until For 24 hours, he must refrain from putting weight on his leg (walk with a cane) and to control pain, only paracetamol is allowed to be used. After one week, patients will be contacted and questions will be asked about possible side effects.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Akhtar hospital
Full name of responsible person
Ali Asghar Alamian
Street address
Tehran - Shariati St. - Paul Rumi St. - Sharifi Menesh St. - Azar Dead End - Akhtar Orthopedic Center
City
tehran
Province
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1964714953
Phone
+98 21 2200 1072
Email
akhtarhospital@sbmu.ac.ir
Web page address
https://amc.sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Reza Rabati
Street address
Tehran<, Skin Research Center, Shahid Beheshti Medical University,Shohada E Tajrish, ghods Sq, Shahrdari St
City
tehran
Province
Tehran
Postal code
1333635445
Phone
+98 21 2274 1507
Fax
+98 21 2274 4393
Email

src@sbmu.ac.ir

Web page address

https://src.sbmu.ac.ir/

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

Sina Hajiaghajani

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Student

Latest degree

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Other areas of specialty/work

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Position

Student

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sinaaghajani1379@gmail.com

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable