

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the safety of intra-articular injection of t-SVF in patients with osteoarthritis of the knee: a clinical trial, controlled and phase I

Protocol summary

Study aim

Investigating the safety of intra-articular injection of t-SVF in patients with knee osteoarthritis

Design

A clinical study has a control group and a parallel group, randomized by envelope and block method for 20 patients.

Settings and conduct

The leading study presents a new cell therapy approach for cartilage tissue repair in patients with osteoarthritis. Also, this study will be conducted in Tajrish Martyrs Hospital, Shahid Beheshti University of Medical Sciences. 20 patients will be randomly selected based on the inclusion and exclusion criteria. In the intervention group, t-SVF isolated from adipose tissue will be autologously injected intra-articularly for 10 patients. Patients of the control group (10 people) will receive hyaluronic acid hydrogel, which is commercially available, in the form of joint injections.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 50 to 75 years with grade 2 and 3 osteoarthritis and WOMAC test less than 8 in the knee without underlying disease or medical intervention in the past. Exclusion criteria: •Damage to Minsk •Severe swelling and inflammation in the knee area •Rupture of knee ligaments •Pain caused by dislocation or fracture of kneecap •People who have a history of systemic diseases, including diabetes, bleeding disorders. •Women who were pregnant during the study or were planning to become pregnant. •People who have received oral steroids for a long time. •History of any chemotherapy or radiation therapy in both parts of the knee and the fat tissue donor area

Intervention groups

Intervention group: injection of t-SVF into the knee joint.
Control group: injection of hyaluronic hydrogel into the knee joint

Main outcome variables

Safety of intra-articular injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181205041860N2**

Registration date: **2023-06-10, 1402/03/20**

Registration timing: **prospective**

Last update: **2023-06-10, 1402/03/20**

Update count: **0**

Registration date

2023-06-10, 1402/03/20

Registrant information

Name

Mahboubeh Bohlouli

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the safety of intra-articular injection of t-SVF in patients with osteoarthritis of the knee: a clinical trial, controlled and phase I	
Public title	Evaluation of the safety of t-SVF in osteoarthritis
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Unilateral or bilateral knee osteoarthritis is diagnosed using MRI imaging and is class II, III according to Quaterbridge criteria. There is complete damage to the thickness of the cartilage tissue, whose size is less than 1.5 cm in terms of surface. WOMAC test of the patient should be less than 8 The age of the patient should be between 50 and 75 Body mass index of patients should be between 22 and 37.
Exclusion criteria:	Damage to Minsk There is a complete damage to the thickness of the cartilage tissue, which is more than 1.5 cm in terms of surface. Osteochondritis dissections Parameniscal and Bakers or ganglion cysts Lipoma arborescens Hoffa's pad syndrome Severe swelling and inflammation in the knee area Rupture of knee ligaments Pain caused by dislocation or fracture of kneecap The classification of knee injury should be based on Quterbridge Class IV criteria. Classification of knee injury should be based on Quterbridge class IV criteria, but the size of the lesion should be more than 1.5 cm. People who have been injected with drugs such as corticosteroids, Vasosupplementation and cell products including SVF, stem cells, platelet-enriched plasma in the last 6 months. People who have had knee surgery in the last 6 months. People who have a history of systemic diseases, including diabetes, bleeding disorders. Women who were pregnant during the study or were planning to become pregnant. People who have received oral steroids for a long time. History of any chemotherapy or radiation therapy in both parts of the knee and the fat tissue donor area
Age	From 50 years old to 75 years old
Gender	Both
Phase	1
Groups that have been masked	No information
Sample size	Target sample size: 20
Randomization (investigator's opinion)	Randomized
Randomization description	In this study, randomization is performed using the block method using SAS software. twenty patient will be involved in the study, which will be classified into two groups. to avoid identifying the last patient by medical staff, 5 blocks with 6 wells will be designed that only 4 wells per each block will be considered. To conceal randomization, each block will be placed in an envelope and all researchers will unaware of the contents of the envelopes. Therefore, a non-study individual was selected to perform all these steps to inform the physician of the result.
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 Shahid Beheshti University of Medical Sciences
Street address	Arabi St, student Blvd, Velenjac
City	Tehran
Province	Tehran
Postal code	1985717443
Approval date	2022-05-15, 1401/02/25
Ethics committee reference number	IR.SBMU.RETECH.REC.1401.083
Health conditions studied	
1	
Description of health condition studied	Osteoarthritis
ICD-10 code	M15
ICD-10 code description	Polyosteoarthritis
2	
Description of health condition studied	Osteoarthritis of the knee
ICD-10 code	M17
ICD-10 code description	Osteoarthritis of knee
Primary outcomes	
1	
Description	

The primary outcome of this study is safety, which will be evaluated with the occurrence of side effects in patients

Timepoint

The patient will be visited one and six days as well as 1 and 6 months after injection. But during this time, if patients have any abnormal clinical symptoms, you will be counseled or visited by telephone or in person.

Method of measurement

In order to check safety, different parameters such as infection, inflammation, formation of fibrotic tissue, local edema, local erythema, pain and mortality will be evaluated through clinical evaluations, blood tests, MRI.

Secondary outcomes

1

Description

Cartilage regeneration

Timepoint

After 6 months of injection

Method of measurement

Clinical evaluations, blood tests, MRI.

Intervention groups

1

Description

The intervention group includes 10 patients who receive autologous and intra-articular t-SVF isolated from adipose tissue.

Category

Treatment - Other

2

Description

The control group includes 10 patients who receive hyaluronic acid hydrogel commercially and intra-articularly

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Dr. Adel Ebrahimpour

Street address

Shahdari St, Tajrish Square

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Sponsors / Funding sources

1

Sponsor

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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

Mahboubah Bohlouli

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Cell Therapy

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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