Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Therapeutic effect of Adipose-derived Stromal Vascular Fraction on Lateral Epicondylitis (Tennis Elbow) disease, A randomized controlled trial

Protocol summary

Study aim

In this study we are aiming to investigate the therapeutic effect of Adipose-derived Stromal Vascular Fraction on the management of lateral epicondylitis (tennis elbow).

Design

A randomized controlled trial with two parallel groups

Settings and conduct

In this randomized clinical trial 54 people diagnosed with chronic external epicondylitis according to the inclusion and exclusion of the study, will be randomly assigned in two groups of SVF (intervention) and the control group with a ratio of 1:1. Injections will be performed in the external epicondyle area. The person assessing the results and the statistical analyst will be blinded to the patient groups.

Participants/Inclusion and exclusion criteria

The main inclusion criteria include: a minimum of four months must have passed since the onset of pain and conservative treatment must have proven ineffective. A minimum of two months must have passed since the last corticosteroid injection. Main exclusion criteria include history of cardiovascular disease such as previous Myocardial Infarction or heart failure; Coagulopathies such as disrupted PT, PTT, INR and elbow pain caused by other musculoskeletal diseases such as rheumatoid arthritis.

Intervention groups

From group A patients, first about 100 mL of adipose tissue is taken in a sterile form through liposuction of the abdominal area. Then, after the cell separation process, the obtained nano fat will be used for injection. Group B patients will receive corticosteroids and normal saline as a control group.

Main outcome variables

The main variable will be elbow function, which is measured based on the QuickDASH (Disabilities of the Arm, Shoulder and Hand) and Mayo Elbow Performance Index questionnaires.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221104056393N3**
Registration date: **2024-01-11, 1402/10/21**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-11, 1402/10/21**
Update count: **0**

Registration date

2024-01-11, 1402/10/21

Registrant information

Name
Pooya Hosseini-Monfared
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 2200 1072
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-01, 1402/09/10

Expected recruitment end date

2024-07-20, 1403/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Therapeutic effect of Adipose-derived Stromal Vascular Fraction on Lateral Epicondylitis (Tennis Elbow) disease, A randomized controlled trial

Public title
Therapeutic effect of Adipose-derived Stromal Vascular Fraction on Lateral Epicondylitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
At least 4 months passed since onset of pain not responding to conservative therapy for 3 months A history of one unsuccessful corticosteroid or PRP injection in the past 3 months (at least 2 months have passed since the injection) The patient has the ability to understand the explanations and registers his oral and written desire in the informed consent form.

Exclusion criteria:
Any history of an injection in the elbow during the past 2 months History of cardiovascular disease such as previous myocardial infarction or heart failure Coagulopathies such as disrupted PT, PTT, INR Pregnancy or breastfeeding Drug users or alcoholics Elbow pain due to other musculoskeletal diseases such as rheumatoid arthritis, fibromyalgia, etc.

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
In this randomized clinical trial study, randomization is carried out by the 4-way box method in which 2 chances are considered for each group, and 2 out of 4 people are randomly entered into each group by the order of visiting the clinic.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, due to the need for liposuction in the Stromal Vascular Fraction (SVF) group, it is not possible to blind the patients to the type of treatment, but the person who collects the patient's information and also the person who analyzes the final data will be blinded to the group allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Shahid Beheshti University of Medical Sciences

Street address
Azar dead end alley, Sharifi Manesh street., Pole Roomi, Tajrish

City
Tehran

Province
Tehran

Postal code
1964714953

Approval date
2023-11-01, 1402/08/10

Ethics committee reference number
IR.SBMU.SRC.REC.1402.020

Health conditions studied

1

Description of health condition studied
Lateral epicondylitis

ICD-10 code
M77.10

ICD-10 code description
Lateral epicondylitis, unspecified elbow

Primary outcomes

1

Description
Elbow function

Timepoint
Before the intervention, 1, 3, 6 months after the intervention

Method of measurement
QuickDASH and MEPI questionnaire

Secondary outcomes

1

Description
The patient's pain level

Timepoint
Before the intervention, 1, 3, 6 months after the intervention

Method of measurement
VAS questionnaire

2

Description
Radiological evaluation of the lesion in the form of CEO tendon lesion measurement
Timepoint
Before the intervention, 6 months after the intervention
Method of measurement
MRI examination by a radiologist

Intervention groups

1

Description
About 100 mL of adipose tissue is taken under sterile condition 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 will be used for injection. The injection will be done for all patients in the external epicondyle area.
Category
Treatment - Other

2

Description
Control group: Patients in the control group will receive corticosteroids and normal saline.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada Tajrish Hospital
Full name of responsible person
Reza Robati
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Reza Robati
Position
Professor
Latest degree
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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
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
Yes - There is 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
Not applicable

Title and more details about the data/document
Information about the main outcome can be shared after making the individuals undetectable

When the data will become available and for how long
Access will be granted 6 months after the results of the study are published.

To whom data/document is available
Researchers and medical specialist

Under which criteria data/document could be used
based on the Ministry of Health and Medical Education criteria for clinical trials

From where data/document is obtainable
Dr. Reza Robati, Dermatology research center, Tajrish, Tehran

What processes are involved for a request to access data/document
The data that support the findings of this study will be available on request from the corresponding author. The data will not be publicly available due to privacy and ethical considerations.

Comments