

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Evaluation of the effectiveness of autologous blood injection and dry needling in the treatment of refractory tennis elbow

Protocol summary

Study aim

Evaluation of the effectiveness of autologous blood transfusion and dry needling in the treatment of refractory tennis elbow

Design

Clinical trial with control group with parallel, randomized groups, phase 3 on 34 patients. The random number table was used for randomization

Settings and conduct

This study is performed in Al-Zahra Hospital in Isfahan. Patients are randomly divided into two groups. The first group will be treated with dry needling method and the second group will be treated with Autologous Blood Injection method. Patients' pain will be measured and compared 1 month and 3 months later.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients 18-70 years old, Pain in the external epicondyle with local tenderness, Positive one of cozen's or middle finger extension tests, History of lateral conservative treatment of epicondylitis and failure to respond to treatment. Exclusion criteria: History of lateral elbow surgery, Patients with chronic regional pain syndrome Inflammatory arthritis or autoimmune diseases, Patients with lateral collateral ligament rupture, Patients with a history of elbow and forearm fractures.

Intervention groups

Intervention group: Patients in this group will be treated with dry needling method. This technique is performed using Hong's fast-in, fast out method and using filament needles 0.30 in 50 mm 20 times in the specified position. Patients in the other group will be treated with the Autologous Blood Injection method. 3 ml of patients' blood is taken from the contralateral antecubital area. The patients' blood is shaken gently to prevent clotting, and then the same 3 ml of the patients' autologous whole blood is injected at the tenderness site. Patients' pain is measured 1 month and 3 months later by a questionnaire.

Main outcome variables

Elbow pain in patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200217046523N3**

Registration date: **2020-08-21, 1399/05/31**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-21, 1399/05/31**

Update count: **0**

Registration date

2020-08-21, 1399/05/31

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

2020-08-21, 1399/05/31

Expected recruitment end date

2020-10-21, 1399/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of autologous blood injection and dry needling in the treatment of refractory tennis elbow

Public title

Treatment of refractory tennis elbow

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Pain in the external epicondyle with local tenderness
Positive one of cozen's or middle finger extension tests
History of lateral conservative treatment of epicondylitis and failure to respond to treatment

Exclusion criteria:

History of lateral elbow surgery
Patients with chronic regional pain syndrome
Inflammatory arthritis or autoimmune diseases
Patients with lateral collateral ligament rupture
Patients with a history of elbow and forearm fractures

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: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, table of random numbers. In this study, reading the table of predefined random numbers (eg, up or down) and the researcher's second default is to consider even numbers for intervention group. The researcher begins to read the numbers in a predetermined manner and the patients are divided.

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 Esfahan university of Medical sciences

Street address

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

City

Isfahan

Province

Isfahan

Postal code

۸۱۳۷۸۶۶۵۱۵

Approval date

2020-04-19, 1399/01/31

Ethics committee reference number

IR.MUI.MED.REC.1399.060

Health conditions studied**1****Description of health condition studied**

Lateral epicondylitis

ICD-10 code

M77.1

ICD-10 code description

Lateral epicondylitis

Primary outcomes**1****Description**

Pain

Timepoint

1 month and 3 months after intervention

Method of measurement

VAS questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients in this group will be treated with dry needling method. This technique is performed using Hong's fast-in, fast out method and using filament needles 0.30 in 50 mm 20 times in the specified position. Patients' pain is measured 1 month and 3 months later by a questionnaire.

Category

Treatment - Devices

2**Description**

Intervention group: Patients in this group will be treated with the Autologous Blood Injection method. 3 ml of patients' blood is taken from the contralateral antecubital area. The patients' blood is shaken gently to

prevent clotting, and then the same 3 ml of the patients' autologous whole blood is injected at the tenderness site. Patients' pain is measured 1 month and 3 months later by a questionnaire.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Razieh Maghroori

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No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Razieh Maghroori

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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Person responsible for updating data

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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

Isfahan University of Medical Sciences website

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