Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 34patients. 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 Autologus 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 extention 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 Autologus 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
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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 extention 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
Isfehan

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 Autologus 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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+98 31 3668 0042
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ramaghroori@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
Street address
No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan
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haghjoo.sh@med.mui.ac.ir
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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Name of organization / entity
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Full name of responsible person
Razieh Maghroori

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Email
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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