

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effect of corticosteroid injection with and without needle on pain intensity in patients with tennis elbow

Protocol summary

Study aim

Determining the effect of corticosteroid injection with and without needling in the treatment of patients with external epicondylitis (tennis elbow)

Design

A clinical trial with two parallel, double-blind, randomized groups was performed on 90 patients using a random number table.

Settings and conduct

A clinical trial with two parallel, double-blind, randomized groups was performed on 90 patients using a random number table. This study is performed in Yazd. In this study, people are divided into two groups of injection with needling and injection alone. In the intervention group, corticosteroid injection is performed along with needling that with the same needle head as the injection intermittent movements of the needle in and out injure the bone cortex to cause local bleeding at the site. This operation was continued for one minute. In the injection group, injection was performed within 15 seconds without needling. The patient's pain is assessed three months and six months after the injection.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all people who are ill and suffering from tennis elbow; Eligible for the injection of corticosteroids
Exclusion criteria: history of rheumatic disease; upper limb problems

Intervention groups

In this study, people are divided into two groups of injection with needling and injection alone. In the intervention group, corticosteroid injection is performed along with needling that with the same needle head as the injection intermittent movements of the needle in and out injure the bone cortex to cause local bleeding at the site. This operation was continued for one minute. In the injection group, injection was performed within 15 seconds without needling.

Main outcome variables

The patient's pain during 3 months and 6 months after

injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161225031559N4**

Registration date: **2021-10-09, 1400/07/17**

Registration timing: **retrospective**

Last update: **2021-10-09, 1400/07/17**

Update count: **0**

Registration date

2021-10-09, 1400/07/17

Registrant information

Name

Seyed Hossein Saeed-Banadaky

Name of organization / entity

Shahid Sadoughi Medical University

Country

Iran (Islamic Republic of)

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saeed@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

2020-05-21, 1399/03/01

Actual recruitment end date

2021-03-10, 1399/12/20

Trial completion date

2021-03-10, 1399/12/20

Scientific title

The effect of corticosteroid injection with and without needle on pain intensity in patients with tennis elbow

Public title

The effect of corticosteroid injection with and without needle on pain intensity in patients with tennis elbow

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All people using active resisted extension painful wrist test and local tenderness in lateral condyle of humerus that have been given a clinical diagnosis of Albo tennis disease And did not respond to conservative treatment

Exclusion criteria:

Concomitant diseases such as radiculopathy History of previous surgery or limb trauma Positive radiographic evidence such as DJD

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Using table of random numbers, 45 patients will be allocated to each of the intervention and control groups. Each participant will be given a number from 1 to 90. One row and one column will be randomly chosen from the table of random numbers; the intersection between this row and column will be the starting point for sampling. A finger will be put on the starting point and will be moved downwards through the table. Because there should be 45 participants in the intervention group and 45 participants in the control group, the two digits at the right side of each number in the table will be considered. The moving of finger will be repeated until 45 participants of the intervention group will be chosen. Duplicate numbers and numbers larger than 90 will not be considered. In this way, it will be found out that which 45 numbers among all of the 90 numbers given to the whole participants will be allocated to the intervention group (e.g. numbers 3, 4, 9, 11, 13, 14, ...). The remaining 45 participants will be automatically put in the control group. After randomization, each of the 90 numbers will be matched with one of the treatment arms. Each treatment arm will be allocated the letter A

or B and these letters will be put in an opaque and sealed pocket. The researcher and the patient will not know any type of injection and only the injecting physician will be aware of the contents of the envelopes and the type of injection.

Blinding (investigator's opinion)

Double blinded

Blinding description

The type of treatment assigned will be indicated by the letters A or B. Only the injecting physician knows the type of treatment. The researcher and the patient are unaware of the type of injection

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences

Street address

Yazd Shahid Sadoughi University of Medical Sciences, Bahonar Sq, Yazd.

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2020-05-11, 1399/02/22

Ethics committee reference number

IR.SSU.MEDICINE.REC.1399.051

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

lateral epicondylitis (tennis elbow)

ICD-10 code

M77.1

ICD-10 code description

Lateral epicondylitis

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

Patient pain rate

Timepoint

3 months and 6 months after injection
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Local corticosteroid injection +1 cc lidocain at the lateral epicondyle of humerus with in situ needling as long as one minute.

Category

Treatment - Other

2

Description

Control group: Local corticosteroid injection +1 cc lidocain at the lateral epicondyle of humerus

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sadra Clinic

Full name of responsible person

Mohammad Hosein Besharati

Street address

Hana Street, Taleghani Aveniu

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Mohammad Hosein Besharati

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

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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