Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Methylprednisolone and Betamethasone on the treatment of lateral epicondylitis in patients referred to Shafaihiaian and Rasoul Akram hospitals in Tehran in 2025;A randomized clinical trial study

Protocol summary

Study aim

The effect of Betamethasone and Methylprednisolone on the treatment of Lateral Epicondylitis

Design

patients are randomly divided into two groups of 18 individuals each. The corticosteroid injections are administered as a single dose. The follow-up duration for patients is 2, 6, and 12 weeks.

Settings and conduct

Patients presenting to the outpatient clinics of Rasool Akram and Shafa Yahyayan Hospitals during the year 2025, who meet the study inclusion criteria and are diagnosed cases of lateral epicondylitis with symptoms lasting between one to six months, will be enrolled in the study. Participants will then be sequentially assigned into two study groups based on pain severity and age. Both the patients and the questionnaire administrator will be blinded to the type of injectable medication administered. Patients will only be informed about the types of medications being used in the study (without knowing which one they receive). Study questionnaires will be completed before the intervention and subsequently at 2, 6, and 12 weeks after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age range : 25 and 60 years Pain intensity ≥ 5 Written informed consent No local interventions such as PRP and no use of NSAIDs, brace, or physiotherapy within 2 m before the start of the study Exclusion Criteria: systemic inflammatory diseases, fibromyalgia syndrome, cervical radiculopathy, or peripheral neuropathy in the upper limb hypersensitivity to corticosteroids ipsilateral medial epicondylitis Ipsilateral carpal tunnel syndrome Pregnancy or lactation History of elbow fracture Coagulation disorders Psychological disorders Presence of a cardiac pacemaker

Intervention groups

A- Methylprednisolone injection B- Betamethasone injection

Main outcome variables

Visual analog scale Quick Disabilities of the Arm, Shoulder and Hand Patient-Rated Tennis Elbow Evaluation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190610043858N1**
Registration date: **2026-04-20, 1405/01/31**
Registration timing: **retrospective**

Last update: **2026-04-20, 1405/01/31**
Update count: **0**

Registration date

2026-04-20, 1405/01/31

Registrant information

Name

Amir Saberi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 9126 7823

Email address

amirsaberi20@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-15, 1404/04/24

Expected recruitment end date

2026-03-14, 1404/12/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Methylprednisolone and Betamethasone on the treatment of lateral epicondylitis in patients referred to Shafaihiaian and Rasoul Akram hospitals in Tehran in 2025;A randomized clinical trial study

Public title

The effect of Methylprednisolone and Betamethasone on the treatment of lateral epicondylitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with lateral epicondylitis: individuals who, within one to six months prior to entering the study, meet at least two diagnostic criteria in the lateral elbow and forearm region, including tenderness over the lateral epicondyle, positive Cozen’s test: pain occurring in the lateral elbow and forearm during wrist extension against resistance, positive Moudley test: pain occurring in the lateral elbow and forearm during middle finger extension against resistance, positive Chair test: pain occurring in the lateral elbow while lifting a heavy object weighing approximately 3 to 5 kilograms. Age range between 25 and 60 years Pain intensity greater than or equal to 5 based on the Visual Analog Scale (VAS) Obtaining written informed consent No receipt of local interventions such as PRP injections for the treatment of lateral epicondylitis within one to six months prior to study entry No use of NSAIDs, braces, or physiotherapy for the treatment of lateral epicondylitis within two weeks prior to the start of the study

Exclusion criteria:

Patients with systemic inflammatory diseases, fibromyalgia syndrome, cervical radiculopathy, or peripheral neuropathy in the upper limb History of allergy to corticosteroids Ipsilateral medial epicondylitis Ipsilateral carpal tunnel syndrome Pregnancy and breastfeeding History of elbow fracture Coagulation disorders or use of anticoagulant medications Patients with psychological disorders Presence of a cardiac pacemaker

Age

From **25 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **36**

More than 1 sample in each individual

Number of samples in each individual: **0**

One or two elbows of a patient

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients are distributed into study groups based on pain intensity and age. Specifically, individuals are categorized by age into two groups: ≤ 40 years and > 40 years. Regarding pain intensity, based on the VAS scale, individuals are categorized into two blocks: ≤ 7 and > 7. They are then sequentially and consecutively assigned to study groups A and B. Individuals aged ≤ 40 years are classified into the above pain intensity categories (Block A and Block B), while individuals aged > 40 years are classified into the same pain intensity categories (Block C and Block D). These categories are labeled with the corresponding Persian letters in the checklist, so the distribution of patients across groups is symbolically represented to maintain consistency.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants are unaware of the type of injectable medication being used. Additionally, a trained orthopedic resident who collects data before and after the intervention is also unaware of the type of intervention being performed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Faculty of Medicine, Iran university of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2025-07-13, 1404/04/22

Ethics committee reference number

IR.IUMS.FMD.REC.1404.207

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 intensity
Timepoint
before and at 2, 6, and 12 weeks after the intervention
Method of measurement
Visual analog scale

Secondary outcomes

1

Description
individual's daily function
Timepoint
before and at 2, 6, and 12 weeks after the intervention
Method of measurement
quick DASH , Patient-Rated Tennis Elbow Evaluation (PRTEE)

Intervention groups

1

Description
Intervention group: A- Local injection of Methylprednisolone (40 mg/mL – Iran Hormone Company) administered at the tendinoperiosteal site approximately 2 cm inferior and anterior to the lateral epicondyle, aligned with the point of maximum tenderness
Category
Treatment - Drugs

2

Description
Intervention group: Local injection of Betamethasone (4 mg/mL – Aburaihan Company) administered at the tendinoperiosteal site approximately 2 cm inferior and anterior to the lateral epicondyle, aligned with the point of maximum tenderness
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasoul Akram Hospital and Shafa Yahyaian Hospital, Te
Full name of responsible person
AMIR SABERI
Street address
SATTAR KHAN- NIAYESH AVE.
City
TEHRAN
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 6435 1000
Email
amirsaberi20@gmail.com

2

Recruitment center
Name of recruitment center
Shafa Yahyaian houspital
Full name of responsible person
AMIR SABERI
Street address
Baharestan Square, Mojahedin-e-Islam Street
City
TEHRAN
Province
Tehran
Postal code
1157637131
Phone
+98 21 3848 7000
Fax
+98 21 3848 7000
Email
amirsaberi20@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
AMIR SABERI
Street address
Sattar Khan, Niayesh Street
City
TEHRAN
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 6435 1000
Email
amirsaberi20@gmail.com
Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Amir Saberi
Position
Md
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Sattar Khan, Niayesh Street
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 6435 1000
Fax
Email
amirsaberi20@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Amir Saberi
Position
Md
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Sattar Khan, Niayesh Street
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 6435 1000
Fax
Email
amirsaberi20@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Amir Saberi
Position
Md
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Sattar Khan, Niayesh Street
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 6435 1000
Fax
Email
amirsaberi20@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Maintaining research ethics
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
No - There is not 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
No - There is not a plan to make this available
Title and more details about the data/document
no data
When the data will become available and for how long
-
To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

What processes are involved for a request to access data/document

-

Comments

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