

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of steroid injection vs dextrose prolotherapy effects in improvement of patients with chronic lateral epicondylitis

#### Protocol summary

##### Study aim

Determining the effect of dextrose prolotherapy vs steroid in improvement of patients with chronic lateral epicondylitis

##### Design

In this study 36 patients with chronic lateral epicondylitis having inclusion criteria referred to Mahdih and Shahid modarres hospital have been chosen and randomly put in injection groups :dextrose prolotherapy or steroid with a given code

##### Settings and conduct

All patients with chronic lateral epicondylitis referring to mahdih and shahid modarres hospital Patients and Assessor are blind to the type of injection

##### Participants/Inclusion and exclusion criteria

All patient with chronic lateral epicondylitis by these inclusion criteria: 1- age range of 18 to 55 2- Positive Cozen test 3- No response to the conservative treatment are included to the study and patients with these exclusion criteria:1- Rheumatologic disease 2- Diabetes melitus 3- Pregnancy4- Cuagulopathy 5-History of trauma and 6- C6,C7 radiculopathy will be excluded.

##### Intervention groups

Steroid injection: control group; Dextrose prolotherapy: intervention group

##### Main outcome variables

The pain intensity by VAS, The physical function and symptoms by quick DASH score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170311033000N3**

Registration date: **2018-02-17, 1396/11/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-02-17, 1396/11/28**

Update count: **0**

##### Registration date

2018-02-17, 1396/11/28

##### Registrant information

###### Name

Masume Bayat

###### Name of organization / entity

Shahid beheshti university of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2273 1112

###### Email address

bayat.masyme@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-08-22, 1396/05/31

##### Expected recruitment end date

2018-12-20, 1397/09/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of steroid injection vs dextrose prolotherapy effects in improvement of patients with chronic lateral epicondylitis

##### Public title

Comparison of steroid injection vs dextrose prolotherapy in patients with chronic lateral epicondylitis

##### Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

All patient having lateral epicondylitis for atleast 3 months All patients having chronic lateral epicondylitis with age range 18 -55 years old All patients having chronic lateral epicondylitis with Cozen positive test All patients having lateral epicondylitis didnt answer to conservative treatment

### Exclusion criteria:

Any kind of injection about the involved elbow during previous 3months C6,C7 radiculopathy in the involved upper limb Cuagulopathy or using anti cuagulants diabetes melitus pregnancy surgery about the involved elbow during previous 3 months Rhumatologic disorder Recent trauma to the involved elbow since 3months ago

## Age

From **18 years** old to **55 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **36**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Block randomization

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Patients as participants and the responsible physician as an assessor of the out comes are blinded to 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 Shahid Beheshti University of Medical Sciences

##### Street address

Ethics committe,Shahid Beheshti University of Medical Sciences, Velenjak street, Teheran, Iran

##### City

Teheran

##### Province

Tehran

##### Postal code

1985717443

##### Approval date

2017-12-24, 1396/10/03

##### Ethics committee reference number

IR.SBMU.MSP.REC.1396.646

## Health conditions studied

### 1

#### Description of health condition studied

chronic lateral epicondylitis

#### ICD-10 code

M77.1

#### ICD-10 code description

Lateral epicondylitis

## Primary outcomes

### 1

#### Description

The pain intensity

#### Timepoint

Before injection , 1month and 3 months after the injection

#### Method of measurement

Asking patients to rate his/her pain in range of 0 -10 based on visual analogue scale

### 2

#### Description

The patient's function score

#### Timepoint

Before injection , 1month and 3 months after the injection

#### Method of measurement

Based on Quick DASH questionarie

### 3

#### Description

The patient's symptoms score

#### Timepoint

Before injection , 1month and 3 months after the injection

#### Method of measurement

Based on Quick DASH questionarie

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: One time injection of 2cc dextrose 16

% made from 4 cc dextrose 20% and 1 cc lidocaine 2% with blue needle by pepering technique in lateral epicondyle region

**Category**

Treatment - Other

**2**

**Description**

Control group: One time injection of solution 1 cc methylprednisolone 40 mg and 1 cc lidocaine with blue needle by pepering technique in lateral epicondyle region

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Mahdieh Hospital

**Full name of responsible person**

Masumeh Bayat

**Street address**

Mahdieh Hospital, Rajab Nia Street, Shishehgar Alley, Fadaian Inslam Street, Shosh Square, Tehran

**City**

Tehran

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1185817311

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bayat.masyme@sbmu.ac.ir

**2**

**Recruitment center**

**Name of recruitment center**

Shahid Modarres Hospital

**Full name of responsible person**

Maryam alsadat Mortazavian Babaki

**Street address**

Shahid Modarres Hospital, Saadat Abad street, Tehran

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maryam\_m.babaky@sbmu.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Physical Medicine and Rehabilitation Department of Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Vice chancellor for research ,Seyed Ahamad Raeis Alsadat

**Street address**

Physical Medicine and Rehabilitation Department, Shahid Modarres Hospital, Kaj square, Saadat abad,Tehran,Iran

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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**

Physical Medicine and Rehabilitation Department of 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**

Maryam alsadat Mortazavian Babaki

**Position**

Physical Medicine and Rehabilitation resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

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## Person responsible for scientific inquiries

### Contact

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**Position**  
Associate professor  
**Latest degree**  
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## Person responsible for updating data

### Contact

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Maryam alsadat Mortazavian Babaki

**Position**  
Physical Medicine and Rehabilitation resident  
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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