Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 reffered to Mahdieh 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 refering to mahdieh 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)

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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

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2

Recruitment center

Name of recruitment center

Shahid Modarres Hospital

Full name of responsible person

Maryam alsadat Mortazavian Babaki

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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

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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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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