

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

A clinical trial to compare injection of dextrose20% and extracorporeal shock wave therapy in treatment of tennis elbow.

Protocol summary

Summary

Objective: to determine the suitable method of treatment in patients with tennis elbow to improve pain and function. type of study: randomized, single blind, study population: age between 18-64 years old: at least 3 months pain in lateral epicondyle: failure of at least one common treatment of tennis elbow: pain and tenderness in lateral epicondyle: tenderness in origin of extensor carpi radialis brevis muscle in 5-10mm distal to lateral epicondyle: pain score in visual analogue scale greater than 4. Exclusion criteria: injection of corticosteroid in previous 6 weeks : previous dextrose injection: neck pain: coagulopathies or anticoagulants intake: pregnancy: concomitant pathology or previous surgery of upper limbs: chronic use of opioids: physiotherapy in previous 8 weeks: diabetes: rheumatologic disorders: history of arthritis: fibromyalgia This study sample size is 30 patients who divide randomly in two groups: one with dextrose 20% injection and another with shock wave. in prolotherapy group (dextrose 20%) the patients are injected one time and follow 1 and 2 months after injection. in shock wave group patients have 3 shock wave therapy sessions weekly and then follow 1 and 2 month after 1st session. the patients assessment is done with Visual Analogue Scale (VAS), DASH questionnaire, grip strength with dynamometer and pressure pain threshold with Algometer .

General information

Acronym

ESWT-Extracorporeal shock wave therapy

IRCT registration information

IRCT registration number: **IRCT2014081718831N1**

Registration date: **2014-09-29, 1393/07/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-09-29, 1393/07/07

Registrant information

Name

Maryam Esmaeili jamkarani

Name of organization / entity

Firuzgar hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1600

Email address

mej3272@yahoo.com

Recruitment status

Recruitment complete

Funding source

Department of physical medicine and rehabilitation, Firoozgar hospital, Iran University of Medical Science.

Expected recruitment start date

2014-09-16, 1393/06/25

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare injection of dextrose20% and extracorporeal shock wave therapy in treatment of tennis elbow.

Public title

Comparison between injection of dextrose20% and shock wave therapy in treatment of elbow pain (tennis elbow)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:age between 18-64 years old:at least 3months pain in lateral epicondyle:failure of at least one common treatment of tennis elbow:pain and tenderness in lateral epicondyl:tenderness in origin of extensor carpi radialis brevis muscle in 5-10mm distal to lateral epicondyl:pain score in visual analogue scale greater than 4. Exclusion criteria:injection of corticosteroid in previous 6 weeks : previous dextrose injection:neck pain:coagulopathies or anticoagulants intake:pregnancy:concomitant pathology or previous surgery of upper limbs:chronic use of opioids:physiotherapy in previous 8 weeks:diabetes:rheumatologic disorders:history of arthritis:fibromyalgia

Age

From **18 years** old to **64 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Science

Street address

Iran University of Medical Science, Hemmat high way, Tehran

City

Tehran

Postal code

Approval date

2014-09-14, 1393/06/23

Ethics committee reference number

93/2889/105/

Health conditions studied

1

Description of health condition studied

Tennis elbow

ICD-10 code

M77.1

ICD-10 code description

Lateral epicondylitis

Primary outcomes

1

Description

Pain score

Timepoint

Before intervention,one month after intervention.two months after intervention

Method of measurement

Visual analogue scale(VAS)

2

Description

The ability of patient to do daily works that need hands to doing them.

Timepoint

before intervention,one month after intervention.two month after intervention

Method of measurement

Quick DASH questionnaire

3

Description

Grip strength

Timepoint

Before intervention,one month after intervention,two months after intervention

Method of measurement

By use of Dynamometer

4

Description

Pressure pain threshold

Timepoint

Before intervention,one month after intervention,two months after intervention

Method of measurement

By use of Algometer

Secondary outcomes

empty

Intervention groups

1

Description

One Injection of Dexrose 20%,3cc with 1cc of lidocain2% in lateral epicondyle of elbow.

Category

Treatment - Other

2

Description

Three session weekly of extracorporeal shock wave therapy in 2Bar and2000pulses in lateral epicondyle of elbow

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical Medicine and Rehabilitation department of Firoozgar Hospital

Full name of responsible person

Maryam Esmaili Jamkarani

Street address

Physical Medicine and Rehabilitation department of Firoozgar Hospital, Behafarin Ave, Vli asr Sq, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Physical Medicine and Rehabilitation department of Firoozgar Hospital

Full name of responsible person

Bijan Forough MD,manager of Physical Medicine and Rehabilitation department of Firoozgar Hospital

Street address

Physical Medicine and Rehabilitation department, Firoozgar Hospital , Behafarin Ave,Valiasr Sq,Tehran

City

Tehran

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 Firoozgar Hospital

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Physical Medicine and Rehabilitation, Firoozgar Hospital

Full name of responsible person

Maryam Esmaili Jamkarani

Position

Physical Medicine and Rehabilitation assistant

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Assistant

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty