

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Efficacy of extracorporeal shock wave therapy in the treatment of lateral epicondylitis in athletes using ultrasonography

Protocol summary

Study aim

Efficacy of extracorporeal shock wave in the treatment of lateral epicondylitis in athletes using ultrasonography

Design

A randomized, double-blind randomized clinical trial with a sham group with a sample size of 25 patients.

Settings and conduct

Study Location: Sports Medicine Federation Step 1: Clinical examination Step 2: Complete the informed consent form Step 3: Complete the questionnaire including personal details Step 4: Perform ultrasonography Step 5: Complete the Visual Analogue Scale and Disabilities of the Arm, Shoulder, and Hand Questionnaire, strength hand grip Measurement Step 6: Implementation of the treatment. Two groups studied (experimental, sham), double blind study (the evaluator and the investigator are not aware and only the operator knows the status of the groups). Step 7: Assess the effect of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Confirmation of lateral epicondylitis, at least 3 months of pain in the area, treatment of the affected area for up to 3 months, visual analogue Scale greater than 4. Exclusion criteria: Age less than 18 years old, Contraindication of shock wave, history of lateral epicondial surgery, elbow deformity, cervical radiculopathy, History of rheumatologic diseases, history of shock wave treatment in 12 months Past or injection in the last 3 months.

Intervention groups

An experimental group: a 4 Hz frequency shock wave, an energy flux density of 0.08 J/mm², 2000 Shock, once a week for 3 weeks The Sham group: a 4 Hz frequency shock wave, and energy flux density of 0.04 J/mm², 1500 Shock, once a week for 3 weeks with foam in the area. Physical therapy is then performed with stretching exercise, 3 times a day and 4-5 repetitions.

Main outcome variables

Visual Analogue Scale Score, Disabilities of the Arm,

Shoulder, and Hand Questionnaire Score, strength hand grip score, Check the thickness of the muscle.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190626044015N1**

Registration date: **2019-08-04, 1398/05/13**

Registration timing: **prospective**

Last update: **2019-08-04, 1398/05/13**

Update count: **0**

Registration date

2019-08-04, 1398/05/13

Registrant information

Name

Khadijeh Hosseinzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2211 6998

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of extracorporeal shock wave therapy in the treatment of lateral epicondylitis in athletes using ultrasonography

Public title

Efficacy of shock wave therapy in the treatment of tennis elbow in athletes using sonography

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosed lateral epicondylitis At least 3 month of pain on lateral epicondyle Treatment to the affected area within the previous 3 month VAS above 4 Age between 2 and 4 years

Exclusion criteria:

< 18 year of age Contraindications for shockwave therapy (malignancy, history of infected area involved, epilepsy, epilepsy, use of pacemaker, pregnancy) History of lateral epicondylitis surgery Elbow deformity Cervical radiculopathy History of rheumatology or polyarthritis The history of vasculitis The history of treatment with Shakviou in the last 12 months History of injection in the last 3 months (Corticosteroid, Autologous blood injection, PRP, Mesotherapy) Congenital or acquired deformities of the upper extremity

Age

From **18 years** old to **36 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **25**

More than 1 sample in each individual

Number of samples in each individual: **2**

Given that lateral epicondylitis can be one-way or two-sided, if there is an Inclusion and Exclusion Criteria on both elbows (for example, if the elbow has injected a side of less than 3 months, then this position does not participate in the research) One person can have two samples.

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization by lottery means that at the beginning of the study and in the first referring patient, the group names are written in 2 pieces of paper and placed in one of two intervention or control groups by the patient operator's removal. By identifying the first patient's treatment group, the next patient will be assigned to the other group and thus the patients will be divided into groups. In this study, the researcher,

evaluator, and participants are unaware of the study group allocation and only the operator is aware of the group assignment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants enter the research after completing the informed consent form and are divided into two groups. From this stage, only the operator of the device has been informed from the medical group and the participants, the researcher and the evaluator to avoid the bias in the study from the subjects of the study groups No information is available.

Placebo

Used

Assignment

Parallel

Other design features

Examples include athletes who are brought to the attention of sports federations, who will begin treatment with the approval of the center.

Secondary Ids

empty

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

Ethics committee of shiraz university of medical science

Street address

No. 10, Payvand 21., Payam Blvd., Paknejad Bvd., Saadatabad

City

Tehran

Province

Tehran

Postal code

۱۹۸۱۹۴۴۱۵

Approval date

2019-03-12, 1397/12/21

Ethics committee reference number

IR.SEMUMS.REC.1398.002

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

Lateral Epicondylitis or Tennis Elbow

ICD-10 code

M77.1

ICD-10 code description

Lateral epicondylitis

Primary outcomes

1

Description

Measurement of tendon thickness

Timepoint

Before the intervention begins and one month after the end of the intervention

Method of measurement

Ultrasonography

Secondary outcomes

1

Description

Pain score

Timepoint

At the beginning of the study (before the intervention), after the end of the intervention and one month after the end of the intervention

Method of measurement

Visual Analogue Scale

2

Description

Performance score

Timepoint

Before the intervention begins, after the intervention and one month after the end of the intervention

Method of measurement

Disabilities of the Arm, Shoulder, and Hand Questionnaire

3

Description

hand strength score

Timepoint

Before the intervention begins, after the intervention and one month after the end of the intervention

Method of measurement

Dynamometer

Intervention groups

1

Description

Intervention group: a 4 Hz frequency shock wave, an energy flux density of 0.08 J/mm², 2000 Shock, once a week for 3 weeks. Physical therapy is then performed with stretching exercise, 3 times a day and 4-5 repetitions. Shock wave unit: ESM /SWISS DOLORCLAST/ Switzerland

Category

Rehabilitation

2

Description

Control group: Sham group, a 4 Hz frequency shock wave, an energy flux density of 0.04 J/mm², 1500

shocks, once a week and for 3 weeks with foam mediator in the area. Also physiotherapy with stretching exercises for 3 times Performs 4-5 repetitions per day.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sports Medicine Federation

Full name of responsible person

Dr. GholamReza Norouzi

Street address

Sports Medicine Federation, Varzandeh Ave, South Mofateh Ave, 7 Tir

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Atefeh Aminianfar

Street address

School of rehabilitation, Semnan University of Medical Sciences, 5 km of Semnan-Damghan road

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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

Semnan 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**

Semnan University of Medical Sciences

Full name of responsible person

Dr. Atefeh Aminianfar

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Dr. Atefeh Aminianfar

Position

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Latest degree

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Other areas of specialty/work

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