

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### The effect of shock wave therapy combined with topical corticosteroid on severity of pain and grip strength of patient with lateral epicondylitis.

#### Protocol summary

##### Study aim

Determine the effectiveness of shock wave combination therapy and local corticosteroid with shock wave alone on severity of pain and grip strength in patients with lateral epicondylitis

##### Design

A clinical trial with a control group, with a parallel group, double blind, randomized

##### Settings and conduct

This study is performed on 70 people in Physical medicine clinics affiliated to Isfahan University of Medical Sciences. Patients are initially examined by a physical medicine specialist and, if there is a typical biography, tenderness is placed at the site of the extensor tendons to the lateral epicondyl, and at least one of the relevant tests (Thamsen test and Maudsley, s test) is diagnosed. Both groups of patients receive routine lateral epicondylitis treatment with Scan View 3 sessions per week.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years! Duration of the disease is more than 3 months! Failure to respond to a non-invasive conservative treatment! Exclusion criteria: Patient dissatisfaction; pregnancy during the course of treatment; malignant infections or need surgery in the arterial region; arthritis; generalized polyarthritis; dysfunction of the shoulder on the same side

##### Intervention groups

In the study, one group received topical clobutazol ointment and another group received a vaseline.

##### Main outcome variables

Pain intensity; grip strength

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171030037093N8**

Registration date: **2019-05-04, 1398/02/14**

Registration timing: **prospective**

Last update: **2019-05-04, 1398/02/14**

Update count: **0**

##### Registration date

2019-05-04, 1398/02/14

##### Registrant information

###### Name

Sadra Ansaripour

###### Name of organization / entity

Shahrekord University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3650 3487

###### Email address

st\_ansari.s@skums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-31, 1398/03/10

##### Expected recruitment end date

2019-08-01, 1398/05/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of shock wave therapy combined with topical corticosteroid on severity of pain and grip strength of patient with lateral epicondylitis.

##### Public title

Effect of sockwave and corticosteroid on epicondylitis

## Purpose

Diagnostic

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age over 18 years Duration of the disease is more than 3 months Failure to respond to a non-invasive conservative treatment

### Exclusion criteria:

Patient dissatisfaction pregnancy during the course of treatment malignant infections or need surgery in the arterial region arthritis eneralized polyarthritis dysfunction of the shoulder on the same side

## Age

From **18 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **70**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients are randomly assigned to one of the two groups by selecting the cards named A and B.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The topical clobetasol ointment and vaseline are coded by similar collaborators in the same packages, and the first group is packed with the code A and the second group receives the packet B of the packet with closed bandages, so that the participants and the researchers are blind to the contents of the packets.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

##### Street address

Isfahn University of Medical Sciences, Hezar jarib st, Isfahan

##### City

Isfahan

## Province

Isfahan

## Postal code

7346181746

## Approval date

2019-03-18, 1397/12/27

## Ethics committee reference number

IR.MUI.MED.REC.1398.011

## 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 the intervention and two months after the intervention

#### Method of measurement

Graded line of Visual Analogue Scale (VAS)

### 2

#### Description

Grip strength

#### Timepoint

Before the intervention and two months after the intervention

#### Method of measurement

Dynamometer

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: treated with shockwave with topical clobutazol half an hour before the shockwave meetings. Patients undergoing lateral epicondylitis routine treatment with shockwave receive 3 sessions per week. ointment

#### Category

Treatment - Devices

## 2

### Description

Control group: Treated a shockwave with vaseline half an hour before the shockwave meetings. Patients undergoing lateral epicondylitis routine treatment with shockwave receive 3 sessions per week.

### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Physiotherapy and Rehabilitation Clinics of Isfahan University of Medical Sciences

##### Full name of responsible person

Babak Vahdatpour

##### Street address

Office of Physical Medicine and Rehabilitation, Al-Zahra Educational Center, ,Sofe St., Isfahan, Iran

##### City

Isfahan

##### Province

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##### Postal code

8174675731

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+98 31 3670 0666

##### Email

vahdatpour@med.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Ziba Farajzadegan

##### Street address

Isfahan University of Medical Sciences, Hezar jarib Avne

##### City

Isfahan

##### Province

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##### Postal code

7346181746

##### Phone

+98 31 3668 0048

##### Email

Farajzadegan@med.mui.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

##### Full name of responsible person

Babak Vahdatpour

##### Position

Associate Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Physical Medicine

##### Street address

Department of Physical Medicine and Rehabilitation, School of Medicine, Kashani Hospital, Isfahan University of Medical Sciences

##### City

Isfahan

##### Province

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##### Postal code

8174675731

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vahdatpour@med.mui.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Esfahan University of Medical Sciences

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Associate Professor

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## Person responsible for updating data

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vahdatpour@med.mui.ac.ir

## 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**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not 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**

Information about the main outcome can be shared.

**When the data will become available and for how long**

Start the access period 4 months after publishing the results

**To whom data/document is available**

Researchers working in academia

**Under which criteria data/document could be used**

Use data to complete clinical trial studies

**From where data/document is obtainable**

Department of Physical Medicine and Rehabilitation

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

After the investigation of researcher request and presentation of required documents will be accessible.

**Comments**