

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 Ansari pour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

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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

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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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

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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

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

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

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Person responsible for updating data

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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

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