

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Extracorporeal shockwave effect on treatment of post-surgical pillar pain in patients with carpal tunnel syndrome

Protocol summary

Study aim

DETERMINING THE EFFECT OF ESWT ON TREATMENT OF POST-SURGICAL PILLAR PAIN IN PATIENTS WITH CARPAL TUNNEL SYNDROME

Design

In this research, 32 eligible patients referring from a single orthopedist were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

Referred patients divided in either shockwave or sham group blindly(after being informed about the process and the blindness) and then enrolled for 4 sessions of ESWT in Isfahan Kashani hospital.

Participants/Inclusion and exclusion criteria

patients with persistent palmar pain for at least one month after surgery(visual analogue score (VAS) more than 5 points) and not improved after 10 sessions of physical therapy will be included. pregnancy, infection at the site or coagulopathy exclude the patients from the study.

Intervention groups

Half of the patients undergo four treatments of ESWT, performed at weekly intervals using Duolith sd1 shockwave equipment with an average of 2800 shocks and very low EFD of 0.03 mj/mm² at first session. The energy will be increased during the next three sessions according to patients' tolerance. The pulse repetition frequency is 4 Hz. The other half undergo four sessions of sham shockwave with the same number of shocks and session intervals as the case group but with no energy.

Main outcome variables

Reduction in pillar pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171109037338N1**

Registration date: **2018-01-07, 1396/10/17**

Registration timing: **retrospective**

Last update: **2018-01-07, 1396/10/17**

Update count: **0**

Registration date

2018-01-07, 1396/10/17

Registrant information

Name

Adele Oreizi

Name of organization / entity

isfahan univesity of medical science

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-06-30, 1395/04/10

Expected recruitment end date

2017-11-01, 1396/08/10

Actual recruitment start date

2016-07-31, 1395/05/10

Actual recruitment end date

2017-11-01, 1396/08/10

Trial completion date

empty

Scientific title

Extracorporeal shockwave effect on treatment of post-surgical pillar pain in patients with carpal tunnel syndrome

Public title

Extracorporeal shockwave effect on post-surgical pain
carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who have persistent palmar pain for at least one month after carpal tunnel release surgery Visual Analog Scale >5 Pain has not been improved with physical therapy.

Exclusion criteria:

Infection at the site of treatment Pregnancy Patients who have history of coagulopathy. Patients who have systemic disease with joint involvement such as gout, rheumatoid arthritis.

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **32**

Actual sample size reached: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are divided to two groups using table of random numbers with the simple randomization method.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants were explained about the process initially and told that they may be either in shockwave or sham group but they would not know it.

Placebo

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

Hezar jarib

City

isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2016-06-15, 1395/03/26

Ethics committee reference number

IR.MUI.REC.1395.3.404

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

Carpal tunnel syndrome, pillar pain, Extracorporeal shockwave therapy

ICD-10 code

G56.00

ICD-10 code description

Carpal tunnel syndrome, unspecified upper limb

Primary outcomes**1****Description**

The intensity of pain in patients with pillar pain

Timepoint

before intervention and 1 and 3 months after intervention

Method of measurement

Visual Analogue Scale

2**Description**

Evaluation of patients hand function

Timepoint

before intervention and 1 and 3 months after intervention

Method of measurement

Brief-Michigan hand questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: four treatments of extracorporeal shockwave therapy (ESWT), performed at weekly intervals using Duolith sd1 shockwave equipment with an average of 2800 shocks and very low EFD of 0.03 mJ/mm² at first session. The energy will be increased during the next three sessions according to patients' tolerance. The pulse repetition frequency is 4 Hz.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Adele Oreizi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Movahedian attar

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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

Adele Oreizi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Individual participant data

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Available for people working in academic institutions

Under which criteria data/document could be used

No other criteria

From where data/document is obtainable

Adele Oreizi 00989133108477

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

The applicant should send by E-mail the request accompanied with a certificate of the university or institute where he works and the field of study. If approved, data will be sent in 1 week.

Comments