

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluating the effectiveness of extracorporeal shockwave therapy on pain reduction and function improvement in chronic achilles tendinopathy patients: a randomized clinical trial.

#### Protocol summary

##### Summary

**Aim:** Evaluating the effect of shockwave therapy for treatment of chronic Achilles tendinopathy  
**Inclusion criteria:** at least six months of pain and tenderness of the Achilles tendon; existence of a swollen and painful area on the Achilles tendon; having pain along with plantar flexion in the ankle; having pain in the exacerbated dorsiflexion condition in the ankle  
**Exclusion criteria:** Receiving extracorporeal shockwave lithotripsy during the past 6 months; Local injection of steroids during the past 3 months; Having associated diseases such as Polyneuropathy; Patient's unwillingness to continue the treatment; using another type of treatment; changing the treatment plan based on the physician's opinion  
This study is a double-blind controlled randomized clinical trial. Sample size: 40 patients who referred to physical rehabilitation clinic of the Isfahan University of Medical Sciences and were divided into two groups of 20  
**Intervention:** Weekly shockwave for 4 weeks for the intervention group and shockwave with no energy for the control group  
**Expected outcome:** Pain reduction and improvement of performance which were measured using VAS and AOFAS methods  
**Blinding method:** One group will receive shock wave with the intended energy and the other with zero energy meaning that the shock wave probe is only placed on the trigger and the sound of shock wave is played but the energy is zero. During the analysis, the researcher would collect the data without knowledge about which of the a or b groups received which treatment. Also, conservative treatment and corrective exercises will be administered for both groups during the study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016051727907N1**

Registration date: **2017-07-02, 1396/04/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-07-02, 1396/04/11

##### Registrant information

###### Name

Hadi Foroozan

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3669 1672

###### Email address

hadi\_faroozan@mail.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences, vice chancellor for research

##### Expected recruitment start date

2015-03-01, 1393/12/10

##### Expected recruitment end date

2016-03-01, 1394/12/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the effectiveness of extracorporeal shockwave therapy on pain reduction and function improvement in chronic achilles tendinopathy patients: a randomized clinical trial.

**Public title**

Shock wave therapy for treatment of chronic achilles tendinopathy.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: at least six months of pain and tenderness of the Achilles tendon; existence of a swollen and painful area on the Achilles tendon; having pain along with plantar flexion in the ankle; having pain in the exacerbated dorsiflexion condition in the ankle Exclusion criteria: Receiving extracorporeal shockwave lithotripsy during the past 6 months; Local injection of steroids during the past 3 months; Having associated diseases such as Polyneuropathy; Patient's unwillingness to continue or lack of cooperation; using another type of treatment; changing the treatment plan based on the physician's opinion

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

Patients were randomly allocated into two groups using random numbers table developed by Random Allocation Software

**Secondary Ids**

empty

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

Ethics Committee of Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Hezar Jerib

Street

**City**

Isfahan

**Postal code**

7346181746

**Approval date**

2014-12-10, 1393/09/19

**Ethics committee reference number**

IR.MUI.REC.1394.3.077

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

Achilles tendinopathy

**ICD-10 code**

M76.60

**ICD-10 code description**

Achilles tendinitis, unspecified leg.

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

Performance

**Timepoint**

Before intervention/ Immediately after, 1 month and 4 months after intervention.

**Method of measurement**

The American Orthopedic Foot and Ankle Score

**2****Description**

Pain

**Timepoint**

Before intervention/ Immediately after, 1 month and 4 months after intervention.

**Method of measurement**

Visual Analogue Scale

**Secondary outcomes**

empty

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

Intervention group: 4 session of shock wave weekly. Focused: 1500, Energy: 0.25-0.4 Frequency: 2-3 HZ Radial: 3000, Energy: 1.8-2.6 Frequency: 21Hz In addition to conservative treatment including: Therapeutic exercise, local massage, and daily use of 100 mg diclofenac sodium for 2 weeks.

**Category**

Other

## 2

### Description

Control group: 4 session of SHAM shock wave weekly.  
Focused: 1500, Energy:0 Frequency: 2-3 HZ Radial:  
3000, Energy: 0 Frequency: 21Hz In addition to  
conservative treatment including: Therapeutic exercise,  
local massage, and daily use of 100 mg diclofenac  
sodium for 2 weeks.

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Physical Medicine and Rehabilitation Clinic, Al-Zahra  
Hospital

##### Full name of responsible person

Hadi Foroozan

##### Street address

Soffeh Avenue

##### City

Isfahan

### 2

#### Recruitment center

##### Name of recruitment center

Physical Medicine and Rehabilitation Clinic, Kashani  
Hospital

##### Full name of responsible person

Hadi Foroozan

##### Street address

Kashani Avenue

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

vice chancellor for research, Isfahan University of  
Medical Sciences

##### Full name of responsible person

Mansour Siavash

##### Street address

Vice Chancellor of Research, Isfahan University of  
Medical Sciences, Hezar Jerib street

##### City

Isfahan

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

vice chancellor for research, Isfahan University of

Medical Sciences

##### 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

Isfahan University of Medical Sciences

#### Full name of responsible person

Hadi Foroozan

#### Position

Resident of Physical Medicine and Rehabilitation

#### Other areas of specialty/work

#### Street address

Department of Physical Medicine and Rehabilitation,  
Al-Zahra Hospital

#### City

Isfahan

#### Postal code

#### Phone

+98 31 3668 5555

#### Fax

#### Email

hadi\_faroozan@resident.mui.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Isfahan University of Medical Sciences

#### Full name of responsible person

Babak Vahdatpour

#### Position

Assistant Professor

#### Other areas of specialty/work

#### Street address

Department of Physical Medicine and Rehabilitation,  
Al-Zahra Hospital

#### City

Isfahan

#### Postal code

#### Phone

+98 31 3668 5555

#### Fax

#### Email

vahdatpour@med.mui.ac.ir

#### Web page address

## Person responsible for updating data

### Contact

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Hadi Foroozan

**Position**

Resident of Physical Medicine and Rehabilitation

**Other areas of specialty/work****Street address**

Department of Physical Medicine and  
Rehabilitation, Al-Zahra Hospital

**City**

Isfahan

**Postal code****Phone**

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**Fax****Email**

hadi\_faroozan@resident.mui.ac.ir

**Web page address**

## 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*