

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

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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

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Person responsible for scientific inquiries

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Babak Vahdatpour

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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