Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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 Rehabilitaion 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 Rehabilitaion Clinic, Kashani Hospital
Full name of responsible person
Hadi Foroozan
Street address
Kashani Avenue
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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
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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 Reahabilitation
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Person responsible for scientific inquiries

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Isfahan University of Medical Sciences
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Babak Vahdatpour
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Assistant Professor
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Person responsible for updating data

Contact

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Position
Resident of Physical Medicine and Rehabilitation

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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