

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### Comparison between Pneumatic Radial Shock Wave and Electromagnetic Radial Shock Wave on Pain and Disability Index in Patients with Plantar Fasciitis.

#### Protocol summary

##### Study aim

Comparison between Pneumatic Radial Shock Wave and Electromagnetic Radial Shock Wave on Pain and Disability Index in Patients with Plantar Fasciitis.

##### Design

A Quasi-experimental trials with 2 treatment groups with sample size including 36 patients and single blind. Patients through Random Table Number are divided by 2 groups. In the studied patients, special group sequentially enter in the dark envelopes. The envelopes is opened by researcher and patient is not aware of the treatment groups.

##### Settings and conduct

A study is conducted at the Khatam Al Anbia Physiotherapy Clinic. The patients with having inclusion criteria after referring to the clinic, randomly divided into Pneumatic Radial Shock Wave and Electromagnetic Radial Shock Wave. After completing the consent form and the initial assessment, the patients based on their group, will receive 5 treatment sessions. The Participants are blind to the treatment groups but researcher that is an evaluator is not blind to the treatment groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: women and men 23 to 61 years with Plantar Fasciitis with symptoms at least 3 months;  
Exclusion criteria: bilateral Plantar Fasciitis, Arthritis: Ankylosing Spondylitis, Diabetes, Cardiac Arrhythmia or Pacemaker, Vascular Disease, History of trauma or foot fracture, Infection or open wound on the heel, Radiculopathy, Neuropathy, Tarsal Tunnel Syndrome, Anticoagulant Therapy, History of fascia surgery, Malignancy, Pregnancy, History of Physiotherapy at 3 months ago, History of injection at 6 months ago, History of treatment with Shock Wave, Foot or Ankle, Athletes

##### Intervention groups

For the patients in the first group, 5 sessions treatments with Pneumatic Radial Shock Wave and in the second

group, 5 sessions treatments with Electromagnetic Radial Shock Wave are used.

##### Main outcome variables

Pain; Disability Index

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180924041111N1**

Registration date: **2018-10-21, 1397/07/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-10-21, 1397/07/29**

Update count: **0**

##### Registration date

2018-10-21, 1397/07/29

##### Registrant information

##### Name

Elham Rahbaran

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3224 3803

##### Email address

rahbaran\_elhamm@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-12-06, 1396/09/15

##### Expected recruitment end date

2018-12-06, 1397/09/15

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison between Pneumatic Radial Shock Wave and Electromagnetic Radial Shock Wave on Pain and Disability Index in Patients with Plantar Fasciitis.

**Public title**  
Comparison between Pneumatic Radial Shock Wave and Electromagnetic Radial Shock Wave on Pain and Disability in Patients with Plantar Fasciitis.

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Women and Men 23 to 61years with Plantar Fasciitis  
Symptoms for at least 3 months  
**Exclusion criteria:**  
Bilateral Plantar Fasciitis Arthritis: Ankylosing Spondylitis  
Diabetes Cardiac Arrhythmia or Pacemaker Vascular Disease Infection or Open Wound on the heel  
Radiculopathy, Neuropathy and Tarsal Tunnel Syndrome  
Anticoagulant Therapy Pregnancy History of recent Fascia Surgery History of Physiotherapy at 3 months ago  
Injection at 6 months ago History of treatment with Shock Wave Malignancy Athletes History of recent trauma or Foot fracture foot or ankle instability

**Age**  
From **23 years** old to **61 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  

- Participant

**Sample size**  
Target sample size: **36**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Simple Randomization through Random Table Numbers

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
After referring to the clinic, a person receives a consent form containing all information related to the purpose and benefits of study and all exclusion and inclusion criteria, which gives patient the right to participate in the study and assures her of retaining all her personal information and give her the right to leave the study if she wishes. The cause of single blindness of the study is that the participants are unaware of the treatment groups but the researcher that is an evaluator, is aware of the treatment groups.

**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

Room 209, 2nd Floor, Building number 4, Isfahan University of Medical Sciences, Hezarjerib Ave

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746-73461

#### Approval date

2017-07-25, 1396/05/03

#### Ethics committee reference number

IR.MUI.REC.1396.3.307

## Health conditions studied

### 1

#### Description of health condition studied

Plantar Fasciitis

#### ICD-10 code

m72.2

#### ICD-10 code description

Plantar fascial fibromatosis

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Before and 1and 5 weeks after the intervention

#### Method of measurement

Visual Analogue Scale

### 2

#### Description

Disability Index

#### Timepoint

Before and 1and 5 weeks after the intervention

#### Method of measurement

foot and ankle ability measure questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1:for the one group, 5 sessions treatments with Pneumatic Radial Shock Wave, 360G, Novin are used.The treatment protocol including:1500 shocks, 1.5 bar at the first session and 2000 shocks, 2 bar at the second session and 2500 shocks, 3bar at the 3 last session

#### Category

Rehabilitation

### 2

#### Description

Intervention group 2: for the second group, 5 sessions treatments with electromagnetic Radial Shock Wave enPULS PRO, Zimmer are used.The treatment protocol including:1500 shocks, 1.5 bar at the first session and 2000 shocks, 2 bar at the second session and 2500 shocks, 3bar at the 3 last session

#### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

khatam Al Anbia

##### Full name of responsible person

Navid Taheri

##### Street address

1st floor, 2nd Jahan Soltan Bldg, Motasham Kashani St, Hakim Nezami Ave

##### City

Isfahan

##### Province

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##### Postal code

8175979663

##### Phone

+98 31 3131 3551

##### Email

n\_taheri@rehab.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Dr. Shaghayegh Haghjoo Javanmard

#### Street address

Isfahan University Of Medical Sciences, Hezarjerib Ave, Isfahan, Iran

#### City

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#### Province

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#### Postal code

81745-73461

#### Phone

+98 31 3668 8138

#### Email

research@mui.ac.ir

#### 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

Navid Taheri

##### Position

Ph.D., Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Physiotherapy

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Isfahan University Of Medical Sciences, Hezarjerib Ave, Isfahan, Iran

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n\_taheri@rehab.mui.ac.ir

## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Navid Taheri

**Position**

Ph.D., Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Navid Taheri

**Position**

Ph.D., Assistant Professor

**Latest degree**

Ph.D.

### **Other areas of specialty/work**

Physiotherapy

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### **Postal code**

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### **Phone**

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### **Email**

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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**

Undecided - It is not yet known if there will be a plan to make this available

### **Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

### **Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available