

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Evaluation of the therapeutic effect of shock wave therapy on pain and function of patients with osteoarthritis of the knee compared to placebo

#### Protocol summary

##### Study aim

Evaluation of therapeutic effect of shock wave therapy on pain and function of patients with osteoarthritis of the knee compared to placebo

##### Design

In this study 50 patients with osteoarthritis of the knee are divided into intervention and control groups. The intervention group is treated with shock wave therapy (3 sessions), local anti pain and hot pack. The control group is treated with sham shock wave (3 sessions), local anti pain and hot pack. The severity of knee pain, knee injury and patient's dysfunction is assessed and compared before intervention and 1, 3 and 10 weeks after intervention by standard questionnaires.

##### Settings and conduct

This study is done in Alzahra, Ayatollah Kashani and Eisabn Maryam hospitals in Isfahan University of Medical Science. Patients with osteoarthritis of the knee who referred to physical medicine and rehabilitation clinics are selected to participate in this study. The intervention group is treated with shock wave therapy (3 sessions), local anti pain and hot pack. The control group is treated with sham shock wave (3 sessions), local anti pain and hot pack. The severity of knee pain, knee injury and patient's dysfunction is assessed and compared before intervention and 1, 3 and 10 weeks after intervention by standard questionnaires.

##### Participants/Inclusion and exclusion criteria

1) Having Osteoarthritis of the knee based on based on American college of Rheumatology, 2)Knee pain, crepitation and joint dryness, 3)Level 2 or 3 in Kellgren Lawrence scale and 4)Patient's willingness to participate in this study

##### Intervention groups

Intervention group: Patients in intervention group are treated with shock wave therapy, local anti pain and hot pack. Control group: Patients in control group are treated with sham shock wave, local anti pain and hot pack.

##### Main outcome variables

Severity of knee pain, knee injury and patient's dysfunction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120729010439N3**

Registration date: **2019-08-14, 1398/05/23**

Registration timing: **retrospective**

Last update: **2019-08-14, 1398/05/23**

Update count: **0**

##### Registration date

2019-08-14, 1398/05/23

##### Registrant information

##### Name

Babak Vahdatpour

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3668 5555

##### Email address

vahdatpour@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-20, 1397/12/01

##### Expected recruitment end date

2019-06-20, 1398/03/30

##### Actual recruitment start date

2019-02-20, 1397/12/01

##### Actual recruitment end date

2019-06-20, 1398/03/30  
**Trial completion date**  
2019-06-20, 1398/03/30

**Scientific title**  
Evaluation of the therapeutic effect of shock wave therapy on pain and function of patients with osteoarthritis of the knee compared to placebo

**Public title**  
Shock wave and osteoarthritis of the knee

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Osteoarthritis of the knee based on based on American college of Rheumatology Knee pain, crepitation and joint dryness Level 2 or 3 in Kellgren Lawrence scale Patient's willingness to participate in this study

**Exclusion criteria:**

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **50**  
Actual sample size reached: **50**

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

**Randomization description**  
Participants were divided in to two groups (Intervention and Control) based on random allocation software.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**  
**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 Science  
**Street address**  
Isfahan University of Medical Science, Hezarjrib Street, Azadi Square, Isfahan City  
**City**  
Isfahan

**Province**  
Isfahan  
**Postal code**  
8174675731

**Approval date**  
2019-02-14, 1397/11/25

**Ethics committee reference number**  
IR.MUI.REC.1397.234

## Health conditions studied

### 1

#### Description of health condition studied

Osteoarthritis of the knee

**ICD-10 code**  
M19.9

**ICD-10 code description**  
Osteoarthritis, unspecified site

## Primary outcomes

### 1

#### Description

The severity of knee pain

#### Timepoint

Before intervention, 1, 3 and 10 weeks after intervention

#### Method of measurement

The Visual Analogue Scale

### 2

#### Description

The severity of knee injury

#### Timepoint

Before intervention, 1, 3 and 10 weeks after intervention

#### Method of measurement

Knee Injury and Osteoarthritis outcome Score Questionnaire

### 3

#### Description

Patient's dysfunction

#### Timepoint

Before intervention, 1, 3 and 10 weeks after intervention

#### Method of measurement

The Lequense questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients in intervention group is treated with shock wave therapy (3 sessions weekly, 1000 shocks with frequency of 406 Hz), local anti pain

(anti pain gel 2 times a day) and hot pack (3 times a day).

**Category**

Treatment - Devices

**2**

**Description**

Control group: Patients in control group is treated with sham shock wave therapy (3 sessions weekly), local anti pain (anti pain gel 2 times a day) and hot pack (3 times a day).

**Category**

Treatment - Devices

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Alzahra Hospital

**Full name of responsible person**

Babak Vahdatpour

**Street address**

Alzahra hospital, Shohadaye Sofeh Sreet, Isfahan city

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vahdatpour@med.mui.ac.ir

**2**

**Recruitment center**

**Name of recruitment center**

Ayatollah Kashani hospital

**Full name of responsible person**

Babak Vahdatpour

**Street address**

Ayatollah Kashani hospital, Kashani street, Isfahan City

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**3**

**Recruitment center**

**Name of recruitment center**

Eisabne Maryam hospital

**Full name of responsible person**

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Fariba Farajzadegan

**Street address**

Isfahan University of Medical Science, Hezarjrib Street, Isfahan City

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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**

Faezeh Mortazavi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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**Latest degree**

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**Other areas of specialty/work**

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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**

No - There is not 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**

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

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable