Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 in to 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

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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

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Province

Isfehan

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 questionnnaire

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

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Alzahra hospital, Shohadaye Sofeh Sreet, Isfahan city

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2

Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

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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
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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