Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Evaluation of therapeutic effect of Electro-Acupressure stimulation in acupuncture points in reducing pain and stiffness and increasing knee joint function in patient with knee osteoarthritis: A randomized clinical trial

Protocol summary

Study aim
Determining the therapeutic effect of electrical stimulation and pressure in acupuncture points in patients with osteoarthritis of the knee referred to the physiotherapy clinic of Pasargad clinic in Shahroud in 2022 and 2023.

Design
A clinical trial with a control group, with three arm parallel groups, triple blind trial, randomized, on 126 patients. The randomizer.org instrument was used for randomization.

Settings and conduct
The intervention is performed in Pasargad physiotherapy clinic in Shahroud. During 10 sessions of treatment, depending on the group in which they are, patients receive simultaneous electrical and pressure stimulation with a TENS-Pen or only pressure stimulation. Stimulation is applied to eight acupuncture points around the knee for one minute at each point. In placebo patients, the tip of TENS-Pen touches the fake points on the skin of the knee without applying pressure or stimulation. Treatment is done daily, five days a week. In all three groups, patients' status is assessed based on WOMAC and KOOS questionnaires and VAS before the first intervention and two days after the last intervention and also in the third week after the last intervention. Only a rheumatologist and physiotherapist is aware of each patient's group. Patients, questionnaire completer and methodologist are not aware of this matter.

Participants/Inclusion and exclusion criteria
inclusion criteria: over 45 years who have suffered from knee osteoarthritis for at least three months. exclusion criteria: stimulation of acupuncture points and use of anticoagulants in the last month, the presence of wound and scratch in acupuncture points, knee surgery or joint injection, advanced neuropathy.

Intervention groups
1. Simultaneous electrical and pressure stimulation 2. Stimulation of pressure 3. Contact of the electrode tip of the device on the fake points (placebo)

Main outcome variables
knee joint pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211123053162N1**
Registration date: **2022-08-31, 1401/06/09**
Registration timing: **prospective**

Last update: **2022-08-31, 1401/06/09**
Update count: **0**

Registration date
2022-08-31, 1401/06/09

Registrant information

Name
Reza Maskani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 23 3239 5054

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2022-09-03, 1401/06/12

Expected recruitment end date

2023-09-03, 1402/06/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effect of Electro-Acupressure stimulation in acupuncture points in reducing pain and stiffness and increasing knee joint function in patient with knee osteoarthritis: A randomized clinical trial

Public title

Therapeutic effect of Electro-Acupressure stimulation in knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 45 years old Patients who have been suffering from osteoarthritis of the knee for at least three months (according to the diagnosis of a rheumatologist).

Exclusion criteria:

Patients who have had a history of acupuncture points stimulation for any purpose in the past month. Patients who have wound, scratch or abnormality in acupuncture points. Patients who have used anticoagulants in the past month and also patients who have had a history of coagulation diseases in the past month. Patients with a history of knee joint surgery (knee replacement). Patients who have advanced neuropathy (pain, burning, tingling in the toes or feet and extreme sensitivity to surface touch). Patients who are drug abuser. Patients who have had any injection into the knee joint in the past month. Patients who had a knee arthroscopy (a type of knee surgery that diagnoses and treats a knee joint problem) for 30 days prior to the intervention. Patients who have unbearable severe pain in the knee that prevents them from participating in the study. Patients with pacemakers. Patients with transplanted tissue. Pregnant patients.

Age

From **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize the samples and assign them to three groups, since the sample size in each group is 42 people, the string of random numbers from 1 to 126, which are classified into three groups, was obtained through the Randomizer.org site and by The methodologist will receive and provide the researcher.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The study is of the triple-blind trial, in such a way that the person completing the questionnaire and entering the data into the SPSS software is not aware of the intervention received by the patients. Also, the groups receiving the intervention and the control group are unaware of their placement in the group. For this purpose, in the control group, the electrode of the device touches the skin of the patient's knee in the areas outside the studied points, without any pressure and also without electric current. In this study, the methodologist is also unaware of the group of each patient in the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Shahroud University of Medical Sciences

Street address

Hafte Tir Square

City

shahroud

Province

Semnan

Postal code

3614773943

Approval date

2022-06-13, 1401/03/23

Ethics committee reference number

IR.SHMU.REC.1401.093

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description
Knee Pain
Timepoint
Before the first session, two days after the last session and three weeks after the last session
Method of measurement
WOMAC and KOOS questionnaire, VAS ruler

Secondary outcomes

1

Description
Knee joint stiffness
Timepoint
Before the first session, two days after the last session and three weeks after the last session
Method of measurement
WOMAC and KOOS questionnaire

2

Description
clinical manifestation of the knee joint
Timepoint
Before the first session, two days after the last session and three weeks after the last session
Method of measurement
WOMAC and KOOS questionnaire

3

Description
Ability to perform daily tasks
Timepoint
Before the first session, two days after the last session and three weeks after the last session
Method of measurement
WOMAC and KOOS questionnaire

4

Description
Physical activity
Timepoint
Before the first session, two days after the last session and three weeks after the last session
Method of measurement
KOOS questionnaire

5

Description
Quality of life
Timepoint
Before the first session, two days after the last session and three weeks after the last session
Method of measurement
KOOS questionnaire

Intervention groups

1

Description
intervention group (1): Simultaneous electrical and pressure stimulation. Patients receive both electrical pulse and pressure simultaneously at eight acupuncture points around the knee during 10 sessions of treatment with a TENS-Pen. Stimulation is performed in each point for one minute. Treatment is performed daily, five days a week for two week.
Category
Treatment - Devices

2

Description
Intervention group (2): acupressure stimulation. In 10 sessions of therapy, they only receive pressure at eight points of acupuncture around the knee with a TENS-Pen. Stimulation is performed in each point for one minute. Treatment is performed daily, five days a week for two week.
Category
Treatment - Devices

3

Description
Control group: placebo. In 10 sessions, the tip of the TENS-Pen electrode touch the fake points around the knee. Electrode contact is made in each point for one minute. This operation is performed daily, five days a week for two week.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein hospital Specialty and subspecialty Polyclinic, Shahroud
Full name of responsible person
Fatemeh Toufan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Mohammad Javad Hashemi
Position
General Physician Intern
Latest degree
A Level or less
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

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

Title and more details about the data/document

Demographic data and results related to the main outcome

When the data will become available and for how long

If the report is published in open access journal, the access period starts 6 months after the article is published.

To whom data/document is available

For all researchers

Under which criteria data/document could be used

If necessary, contact correspond author and if there is a reasonable justification for use in scientific purposes

From where data/document is obtainable

Dr. Reza Maskani, Shahroud, 7thTir Square, Shahroud University of Medical Sciences; School of Nursing and Midwifery 02332395054 maskani.r@shmu.ac.ir

What processes are involved for a request to access data/document

By phone call or by email and registration of the request and stating the reason and purpose of the logical and approved up to two weeks

Comments