Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison between acupuncture with Laser and acupuncture with acupressure on pain and function of patients with knee osteoarthritis.

Protocol summary

Study aim
Comparison between acupuncture with Laser and acupuncture with acupressure on pain and function of patients with knee osteoarthritis.

Design
A clinical trial without a control group with three treatment groups, one-sided blind on 36 patients

Settings and conduct
Patients referred to the physiotherapy clinic of Shahid Beheshti Rehabilitation Faculty and Hakim physiotherapy clinic with matching Three groups of acupuncture treatment. Combination with laser acupuncture points and combination with acupressure blinding the therapist with a separate primary evaluator

Participants/Inclusion and exclusion criteria
Adults aged 40 to 75 years with grade 2 or 3 knee osteoarthritis based on the Kellgren Lawrence criteria, referring to the physiotherapy clinic of Shahid Beheshti Rehabilitation Faculty and Hakim Physiotherapy Clinic • Target population: eligible patients described to enter the study Main entry and exit conditions: Age 40 to 75 years Chronic one-sided knee pain that has lasted for more than 6 months Diagnosis of grade 2 or 3 osteoarthritis BMI: 18.5-29.9 Pain as much as 40 to 90% of the total VAS score Having no contraindications to acupuncture Signs of severe chronic diseases and history of knee surgery, as well as signs of physical therapy in the past six months Absence of patellofemoral joint osteoarthritis

Intervention groups
They are divided into three treatment groups: "acupuncture", "acupuncture and laser acupuncture points" and "acupuncture and acupressure".

Main outcome variables
Primary outcome:Pain level/ Secondary outcomes:The level of physical ability in terms of performance,Movement range of active flexion of the knee,Movement range of active knee extension

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221117056531N1**
Registration date: **2022-12-20, 1401/09/29**
Registration timing: **prospective**

Last update: **2022-12-20, 1401/09/29**
Update count: **0**

Registration date
2022-12-20, 1401/09/29

Registrant information

Name
Aida Zolghadr

Name of organization / entity

Country
Iran (Islamic Republic of)

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aidazolghadr@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date
2023-05-21, 1402/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison between acupuncture with Laser and acupuncture with acupressure on pain and function of patients with knee osteoarthritis.

Public title

Comparison between acupuncture with Laser and acupuncture with acupressure on pain and function of patients with knee arthrosis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 40 to 75 years Chronic one-sided knee pain that has been going on for more than 6 months (33) Diagnosis of grade 2 or 3 osteoarthritis with radiology according to the Kellgren-Lawrence scale (33) diagnosed by the evaluating therapist BMI: 18.5-29.9 The amount of pain as much as 40 to 90% of the total VAS score6.

Exclusion criteria:

Having contraindications for acupuncture (including infection and open wound or cancer) (20) Suffering from other chronic diseases in the critical phase 3. Intra-articular injection, use of knee support, surgery or use of drugs that affect treatment and evaluation. history of joint injections to reduce pain in the past 30 days or the intention to do so during the study (20), attendance during pregnancy and breastfeeding (30) history of performing single or combined treatments or physiotherapy in the last 6 months (17) Having a pacemaker and taking anticoagulant drugs (17) and uncontrolled blood pressure history of surgery in the considered knee (20) radiographic evidence of severe osteoarthritis in the patellofemoral joint

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the researcher who conducts the intervention is blinded, and the allocation of people into three groups and the registration of their characteristics will be done by another person.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Rajaee St

City

تهران

Province

Tehran

Postal code

1373885693

Approval date

2022-11-16, 1401/08/25

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.506

Health conditions studied

1

Description of health condition studied

knee mosteoarthritis

ICD-10 code

M00-M99

ICD-10 code description

اختلال ماهیچه ای استخوانی= آرتروز زانو

Primary outcomes

1

Description

Pain intensity according to VAS

Timepoint

Baseline - first session - sixth session - after three weeks

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Performance change

Timepoint

Baseline - session one - session six - three weeks later

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index Total score

2

Description

changing the range of motion of Aktiochum and opening the knee

Timepoint

Baseline - session one - session six - three weeks later

Method of measurement

By goniometer

Intervention groups

1

Description

First intervention group: Acupuncture - In this group, during six treatment sessions, first 15 minutes of IR rays and then 5 points of acupuncture XI YAN-SP9-GB34-ST35-ST36 are performed for twenty minutes. Eco needle is used in size 2.5 cm long and 0.25 mm in diameter.

Category

Rehabilitation

2

Description

Intervention group 2: Acupuncture and laser acupuncture points - In this group, during six treatment sessions, first 15 minutes of IR rays are received. Then, for 20 minutes, acupuncture points XI YAN-SP9-GB34-ST35-ST36 are subjected to acupuncture with echo needles of 25 mm size and 0.25 mm diameter. Then laser the same points for 5 minutes with MODE parameters; PULSED- PEAK POWER; 150 mW- AVERAGE POWER: 100 mW- DOSE 6 J PER POINT- NUMBER OF POINT 5 is performed with 870M laser of Novin company

Category

Rehabilitation

3

Description

Intervention group 3: Acupuncture and acupressure - in this group, during six treatment sessions, first 15 minutes of IR rays are received. Then, for 20 minutes, acupuncture points XI YAN-SP9-GB34-ST35-ST36 are subjected to acupuncture with echo needles of size 25 mm and 0.25 mm in diameter. Then, for 7 minutes, acupressure on the same points with thumb pressure Therapist's hand is performed for 80 seconds to create a sensation. Then the patient performs active knee movements for 5 minutes

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Rehabilitation Faculty Physiotherapy Clinic

Full name of responsible person

parsa salemi

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damavand st

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2

Recruitment center

Name of recruitment center

Hakim Physiotherapy Clinic

Full name of responsible person

Mojtaba ghala shihini

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aghaei

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aidazolghadr.ot@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

velenjak- 7th floor- bldg no 2- SBMUS- ARABI AVE

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1985717443

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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

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
aida zolghadr

Position
student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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Person responsible for scientific inquiries

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Position
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Latest degree
Bachelor

Other areas of specialty/work
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Person responsible for updating data

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Position
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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
Yes - There is a plan to make this available

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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Part of primary and secondary outcome data

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Industrial and academic researchers

Under which criteria data/document could be used
Personal use of documents is not allowed

From where data/document is obtainable
aidazolghadr.pt@gmail.com email

What processes are involved for a request to access data/document
Send a request to an email address and receive an initial response. Then sending the information by the researcher until one week later

Comments