

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation Outcome of Adding Cupping-therapy to Electro-acupuncture in Accompany with Exercises on Knee Pain, Function and Life Quality at Osteoarthritis

Protocol summary

Study aim

The effect of adding cupping therapy to electroacupuncture with exercise therapy on knee pain and function and quality of life in patients with knee osteoarthritis in sports medicine clinic during 2020-2021

Design

This study is a randomized clinical trial and the analyst does not know the groups. The study is performed in a sports medicine clinic of Imam Hossein hospital and Taleghani hospital. Sampling of patients is done in among patients with osteoarthritis of the knee who refer to a sports medicine clinic and are eligible to participate in the study and are willing to participate in the study.

Settings and conduct

The location of the study is the sports medicine clinic of Imam Hossein Hospital and Ayatollah Taleghani Hospital. Written consent is obtained from the patients to participate in the study. Sampling method will be done by available sampling method and finally, patients will be assigned by lottery from two treatment methods. The sample size of 28 patients in each group is determined. A total of 56 patients with knee osteoarthritis are selected based on the inclusion criteria.

Participants/Inclusion and exclusion criteria

Men and women with knee pain due to osteoarthritis who had knee pain and is now exacerbated.

Intervention groups

We have two groups. Control group receives electroacupuncture and exercise therapy program. In addition to these, intervention group receives cupping. Electroacupuncture is performed for 20 minutes. The intervention group receives the cupping after the electroacupuncture. Number of sessions is twice per week for 4 consecutive weeks.

Main outcome variables

To evaluate the knee pain and function and life quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210216050381N1**

Registration date: **2022-09-03, 1401/06/12**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-03, 1401/06/12**

Update count: **0**

Registration date

2022-09-03, 1401/06/12

Registrant information

Name

Maryam Ganjalikhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2560

Email address

ganjalikhani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2023-04-22, 1402/02/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation Outcome of Adding Cupping-therapy to Electro-acupuncture in Accompany with Exercises on Knee Pain, Function and Life Quality at Osteoarthritis

Public title

Effect of Adding Cupping Therapy to Electroacupuncture in Patients with Knee Osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Men and women over 40 and under 75 years old Body mass index between 18-35 Knee pain for 6 months or more (chronic pain and acutely pain aggravation) Normal neurologic examination Radiology symptoms of osteoarthritis in the knee and at least one osteophyte (grade 2 and 3 criteria of Kellgren Lawrence) in the tibiofemoral joint of the knee

Exclusion criteria:

Knee pain due to problems other than osteoarthritis (rheumatoid arthritis, other rheumatic diseases, etc.) Knee or pelvic replacement surgery in the joint involved or any surgical procedures in the lower extremities during the last 6 months Intra-articular injections of corticosteroids in 6 months, gel and PRP in the last year, the onset of oral opioid or corticosteroid painkillers during the last 4 weeks Physical disorder that prevents a person from doing exercises. Wounds or any lesions caused in knee during treatment sessions (for any reason) taking painkiller other than acetaminophen more than three times at any dose

Age

From **45 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the sample size and number of groups, we write on 28 papers of the control group and 28 papers of the intervention group. We fold the papers so that their writing cannot be read. Then we throw them in the lottery container. The secretary of the clinic, who is not one of the researchers of the project, picks the paper in turn without replacement and is registered in front of the numbers 1 to 56 of the control group and the randomization list is prepared in this way. The next step is to hide the random list. To do this, use opaque sealed envelopes with a random sequence. A number of Sequentially numbered, sealed, opaque envelopes with aluminium wrappers (in order to obscure the contents of the envelopes) are prepared and each of the random numbers is recorded on a card and the cards are placed inside the envelope. In order to maintain a random sequence, envelopes are numbered in the same way on

the outer surface. Finally, the lid of the letter envelopes is glued and placed in a box, respectively. The box is given to the person in charge of reception. Each patient enters the clinic to begin their treatment, take one envelope in order.

Blinding (investigator's opinion)

Not blinded

Blinding description**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

Exercise and sport medicine department, (Ayatollah) Taleghani Educational Hospital ,erabi avenue, velenjak

City

Tehran

Province

Tehran

Postal code

1985711151

Approval date

2021-02-14, 1399/11/26

Ethics committee reference number

IR.SBMU.MSP.REC.1399.702

Health conditions studied**1****Description of health condition studied**

knee osteoarthritis

ICD-10 code

M17.0

ICD-10 code description

Bilateral primary osteoarthritis of knee

2**Description of health condition studied**

Osteoarthritis of knee

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Knee pain

Timepoint

Before intervention and at the end of intervention after eight weeks

Method of measurement

Womac questionnaire, VAS form

Secondary outcomes

1

Description

Quality of life

Timepoint

Before intervention and at the end of intervention at the eight week

Method of measurement

Vas form, WOMAC questionnaire

2

Description

Knee stiffness

Timepoint

Before intervention and at the end of intervention at the eight week

Method of measurement

WOMAC questionnaire, VAS form

Intervention groups

1

Description

Intervention group: In addition to electroacupuncture and exercise therapy, the intervention group receives a cupping. Cupping therapy, patients are treated with a glass cup at the location of the genicular nerves around the knee. Acuzone branding is made in Korea. The cup is placed on the skin and suction is created with its rifle series. It stays on the skin for 5 minutes and then separates from the skin. It is done twice a week for four weeks. In total, eight sessions are done.

Category

Treatment - Devices

2

Description

The control group receives electroacupuncture and an exercise therapy program. Patients are given exercises. Exercises include isometric quadriceps. While lying on back, keep both knees bent and place a pillow or towel between their knees. Gently apply pressure to the pillow. Hold for five seconds and release. patients do the exercises three sets of five repetitions daily. The intensity of the pressure is to the threshold of

pain. Patients also receive electroacupuncture. To do electropuncture: The patient lies on his back on the bed. The site is completely disinfected with an alcohol pad. Electroacupuncture is performed as for 20 minutes (two per week) for a total of 8 sessions. Disposable needles, sterile, 25.25 0. 0.25 mm (disposable needle of Huang Xiu Medical Company, China) will be used in two groups. Electroacupuncture is performed bilaterally and in cases where only one patient has a sore knee, it is performed unilaterally. Acupuncture points are selected according to Chinese acupuncture points. If the patient has a clear trigger point around the knee, a needle should be inserted in this area as well. The needles should not enter the joint space.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein hospital

Full name of responsible person

Maryam saddat Ganjalikhani

Street address

Imam hossein hospital, Imam Hossein square, Madani Ave, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam saddat Ganjalikhani

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Tehran Province, Tehran, Velenjak, 7th Floor, Bldg No.2 SBUMS, Arabi Ave. Iran

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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
 Maryam saddat Ganjalikhani
Position
 Resident
Latest degree
 Medical doctor
Other areas of specialty/work
 Sport Medicine
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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

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

All data is potentially shareable after disabling individuals.

When the data will become available and for how long

Access period starts six months after the article is published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Written request for access to data is possible.

From where data/document is obtainable

For requesting Documents or data correspond to this

address: Taleghani Educational Hospital, Tabnak St.

Velenjak Region, Chamran High Way, Tehran, Iran

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

The applicant requests data or study details and provides the contact address. The data is then made available.

Comments