Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Evaluating the efficacy of electroacupuncture in comparison with physiotherapy for reducing pain and disability in soldiers diagnosed with patellar chondromalacia

Protocol summary

Study aim

Evaluating the efficacy of electroacupuncture compared to physiotherapy in reducing pain and disability in soldiers with chondromalacia patella

Design

44 soldiers diagnosed with chondromalacia patella with predefined criteria were randomly assigned to one of the two groups and treated with 10 sessions of electroacupuncture or physiotherapy. Patients are inhibited to use other medicine and only take 325 mg of acetaminophen daily. In both groups, stretching exercises for the calf and hamstring muscles and strengthening the quadriceps muscles are taught to the patients.

Settings and conduct

The location of the study was Imam Reza Hospital in Tehran, which was a referral and super-specialized hospital, and all stages of the research were carried out in the physical medicine department.

Participants/Inclusion and exclusion criteria

The study inclusion criteria include soldiers who have been diagnosed with chondromalacia patella and have an age range of 17 to 35 years, a disease duration of more than 2 months and no improvement with conservative treatment for at least one month. The diagnosis of chondromalacia patella is based on the clinical description of the patient. Exclusion criteria include a history of lower limb surgery, history of serious knee trauma in the last 6 months or mild trauma in the last 2 months, the presence of any joint damage by examination or X-ray.

Intervention groups

In the electroacupuncture group, patients are treated with acupuncture points ST34, ST36, ST38, SP9, SP10 and GB34. An electroacupuncture device made with a frequency of 5 to 20 Hz and an intensity within the patient's tolerance level that does not cause significant muscle twitching. In the physiotherapy group, patients are treated with 10 sessions of routine physiotherapy with modalities.

Main outcome variables

pain; disability; KOOS questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039323N4**
Registration date: **2023-09-18, 1402/06/27**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-18, 1402/06/27**
Update count: **0**

Registration date

2023-09-18, 1402/06/27

Registrant information

Name

Zahra Rezasoltani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the efficacy of electroacupuncture in comparison with physiotherapy for reducing pain and disability in soldiers diagnosed with patellar chondromalacia

Public title
Evaluating the efficacy of electroacupuncture in comparison with physiotherapy for reducing pain and disability in soldiers diagnosed with patellar chondromalacia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The presence of chondromalacia patella on the basis of patient's history The course of the disease more than 2 months Failure to improve with conservative treatment for at least one month
Exclusion criteria:
History of lower limb surgery History of serious knee trauma in last 6 months or mild trauma in last 2 months The presence of any evidence of internal or external damage to the knee joint by examination or X-ray History of corticosteroid usage History of any systemic disease such as diabetes, rheumatoid arthritis Scar at the acupuncture site The presence of any deformity in the knee joint such as genovarum/genovalgum
Age
From **17 years** old to **35 years** old
Gender
Female

Phase
0
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
For random allocating of two groups with the same size of 20 participants (40 patients in total), we used block randomization with different block sizes. The sizes of blocks would be a multiple of 2 and a divisor of 40. At first, the block sizes were selected randomly. Then, for each block, different permutations for equal group size were determined. Finally, one of the permutations was selected randomly. Random numbers were generated in an independent statistical office using Random Allocation Software Ver 1.0.0.
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 Committees of AJA University of Medical Sciences
Street address
Imam Reza hospital, Etemad zade street, Fatemi street, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1411718546
Approval date
2023-07-17, 1402/04/26
Ethics committee reference number
IR.AJAUMS.REC.1402.086

Health conditions studied

1

Description of health condition studied
Chondromalacia patellae
ICD-10 code
M22.4
ICD-10 code description
Chondromalacia patellae

Primary outcomes

1

Description
pain
Timepoint
Before the intervention, 3 months after the intervention
Method of measurement
The Visual Analogue Scale (VAS) measures pain intensity. The VAS consists of a 10cm line, with two end points representing 0 (‘no pain’) and 10 (‘pain as bad as it could possibly be’).

2

Description
disability
Timepoint
Before the intervention, 3 months after the intervention

Method of measurement
The Visual Analogue Scale (VAS) measures disability intensity. The VAS consists of a 10cm line, with two end points representing 0 (‘no disability ’) and 10 (‘disability as bad as it could possibly be’).

3

Description
Knee Injury and Osteoarthritis Outcome Score (KOOS) Questionnaire
Timepoint
Before the intervention, 3 months after the intervention
Method of measurement
This questionnaire is designed to measure knee pain, symptoms, motor function problems in daily activities, sports, recreation and quality of life in the knee joint. It has 42 patient-centered questions, which examines 5 concepts related to the patient. The subjects used a 5-point Likert scale. There are five options for each question, and the answers are scored from 0 to 4, and the total points obtained in each sub-group are calculated from 0 to 100 points. The number zero indicates the maximum problem and the number 100 indicates the absence of the problem.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the electroacupuncture group, the patients lie on the bed and the treatment is performed at acupuncture points ST34, ST36, ST38, SP9, SP10, and GB34 with 30 x 0.3 mm needles. The needles are kept sterile and with a penetration depth of 10 mm for 20 minutes. Also, an electroacupuncture device made in China is will be used to deliver the current, with a frequency of 5 to 20 Hz and the intensity that is tolerated by the patient without significant muscle twitching. Patients will be prohibited to use any special medicine and only take 325 mg of acetaminophen daily. In both groups, stretching exercises for the calf and hamstring muscles and strengthening the quadriceps muscles will be taught to the patients.
Category
Treatment - Other

2

Description
Control group: In the physiotherapy group, patients were treated with 10 sessions of routine physiotherapy with modalities such as infrared, ultrasound and electrical stimulation. Patients will be prohibited to use any special medicine and only take 325 mg of acetaminophen daily. In both groups, stretching exercises for the calf and hamstring muscles and strengthening the quadriceps muscles will be taught to the patients.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital in Tehran
Full name of responsible person
Reza Kazem Pour Mofrad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Smt.1368@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Artesh 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
Artesh University of Medical Sciences
Full name of responsible person
Zahra Rezasoltani
Position
Associate professor
Latest degree
Specialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
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
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available