Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The survey of the effects of Manual and Electro- Acupuncture on the clinical manifestations and cytokines of immune system in patients with knee osteoarthritis and comparing it with sham acupuncture

Protocol summary

Study aim

Investigating the effect of manual and electrical acupuncture on clinical manifestations and quality of life, as well as immune system cytokines (IL4-IL10-TNFα-TGFβ-IFNγ) of patients with knee osteoarthritis

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, on 45 patients. For randomization, the table of random numbers from the Research randomizer site is used.

Settings and conduct

This study is conducted in the Rheumatology and Acupuncture Clinics of Imam Reza Hospital in Mashhad. After the introduction of the patients by the Rheumatologist and if they are eligible to enter and do not have the exclusion criteria, the patients are randomly divided into three groups. Allocation to groups will be through sealed envelopes and the persons for evaluations and analysts will be blind. The intervention will be conducted and the results will be extracted and analyzed.

Participants/Inclusion and exclusion criteria

Entry criteria: people diagnosed with osteoarthrosis by a rheumatologist; aged 45 to 65 years old; educated and having a pain score of 4 or higher on the VAS scale. Exclusion criteria: people who have knee surgery or arthroscopy or intra-knee injection or disease affecting the immune system; pacemaker; pregnancy; coagulation disorder; mental and cognitive disorders; high weight; joint effusion or severe fear of needles.

Intervention groups

1) manual acupuncture group; 2) electrical acupuncture group; 3) sham acupuncture group

Main outcome variables

Primary outcome: pain; inflammatory factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170305032893N3**
Registration date: **2023-05-02, 1402/02/12**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-02, 1402/02/12**
Update count: **0**

Registration date

2023-05-02, 1402/02/12

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 0915

Email address

khorsanda@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-09, 1402/01/20

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The survey of the effects of Manual and Electro-Acupuncture on the clinical manifestations and cytokines of immune system in patients with knee osteoarthritis and comparing it with sham acupuncture

Public title
Effectiveness of acupuncture in osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients diagnosed with knee OA based on ACR criteria (ACR=American college of Rheumatology)(OA=Osteoarthritis) Age should be between 45 and 65 years old Only one knee is involved Have a VAS pain score of four or more than four.(VAS=visual Analogue scale) Be literate (writing and reading ability)

Exclusion criteria:
The surgery has been detailed or is in the process of surgery Knee arthroscopy has been done during the last year Have an intra-articular injection during the last six months Any disease that disrupts the functioning of the immune system, such as inflammatory diseases, autoimmune diseases, connective tissue diseases, diabetes, cancer, etc. Severe physical or cognitive illness of the participant that prevents the continuation of cooperation Have a pacemaker Pregnancy and breastfeeding Have done acupuncture during the last six months Coagulation disorders and the use of anticoagulants Participation of the candidate in other clinical studies currently or during the last three months Getting infected with covid during the study or ... in the last month or other infectious diseases during the struggle . BMI more than 30 (BMI =body mass index) Any forced changes in treatment regimen Non-cooperation in applying intervention for more than two sessions If the joint has liquid effusion (joint effusion) Life-threatening medical and clinical events Extreme fear of needles(Belonephebia)

Age
From **45 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Online version of the list of random numbers through Research randomizer

Blinding (investigator's opinion)
Triple blinded

Blinding description
Except for the acupuncturist, everyone, including the patients and health personnel, and the outcome assessor and data analyzer, are all blind .First, the randomizer numbers site is asked to divide and present 45 random numbers in three groups A, B and C. Group A is the manual intervention group, and group B is the electrical intervention group, and group C is the sham acupuncture group, and only the acupuncturist intervener is aware of this division .The numbers are placed in sealed envelopes, and after being accepted into the study, the patients refer to the allocator person and take an envelope and refer to the acupuncturist, and after registering the envelope and patient's details, the intervention is performed.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
Qureshi Building, University Street, Mashhad Khorasan razavi

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Mashhad

Province
Razavi Khorasan

Postal code
9177899191

Approval date
2023-01-30, 1401/11/10

Ethics committee reference number
IR.MUMS.REC.1401.371

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
Primary outcome 1) changes in the level of pain based

on the VAS scale before the intervention and weeks 8, 12, and 16.--- . 2) Measuring the amount of inflammatory factors: including IFN-γ (gama interferon)secreted by T-helper1 cells, IL-4 (interleukin-4) secreted by T-helper-2 cells. -- and TGF-β (transforming growth factor beta) and IL10 (interleukin 10)secreted by regulatory T cells (T REG CELLS), and TNFα (tumor necrosis factor alpha)secreted by M1 macrophages before and after treatment at the end of weeks 8 .

Timepoint

0-8-12-16 weeks

Method of measurement

Based on numerical scale of vas and based on laboratory numerical values

Secondary outcomes

1

Description

Changes in the level of physical activity

Timepoint

Before intervention and weeks 8, 12 and 16

Method of measurement

WOMAC Scale(Western Ontario McMaster Universities Osteoarthritis Index)

2

Description

Changes in morning stiffness

Timepoint

Before intervention and weeks 8, 12 and 16

Method of measurement

WOMAC Scale

3

Description

Changes in quality of life

Timepoint

Before intervention and weeks 8, 12 and 16

Method of measurement

Based on the quality of life form (QoL)

Intervention groups

1

Description

Intervention group 1: manual acupuncture group. In this group, acupuncture needles of specific size are used in predetermined and identical points and are stimulated by hand every ten minutes.

Category

Treatment - Devices

2

Description

Control group: Sham acupuncture is performed in the control group, which is actually false. Special Streitberger needles are used, which are placed on the skin. There is a tingling sensation, but the needle does not enter the skin, and the points are the same as in the intervention group.

Category

Treatment - Devices

3

Description

The intervention group 2: In this group, electro-acupuncture is used. The points and needles are the same as the previous group, only the stimulation is done through an electro-acupuncture device with specific voltage and current intensity.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatic Diseases Clinic, Imam Rezai Hospital, Mashhad

Full name of responsible person

Dr. Kamila Hashemzadeh

Street address

Imam Reza Square, Rheumatic Disease Clinic, Imam Reza Hospital, Mashhad

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Email

HashemzadehK@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayour Mobrahan

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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
Mashhad University of Medical Sciences
Proportion provided by this source
1
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
Mashhad University of Medical Sciences
Full name of responsible person
Ahmad Hamzeh
Position
phd student
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Latest degree
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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
Study specific information
When the data will become available and for how long
After completing the study and publication of results
To whom data/document is available
Project supervisors and persons who have permission from the University Research Council
Under which criteria data/document could be used
Project supervisors and persons who have permission from the University Research Council
From where data/document is obtainable
University Research Council
What processes are involved for a request to access data/document
Obtaining the opinion of the research council of the university and obtaining the favorable opinion of the researcher
Comments