

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effectiveness of three treatment methods, TENS, embedding, acupuncture and drug therapy on the level of interleukin 6 and knee osteoarthritis pain.

Protocol summary

Study aim

Determining the effectiveness of three treatment methods: TENS, embedding acupuncture and drug therapy on the level of interleukin-6 and the pain of patients suffering from knee osteoarthritis.

Design

In this study, 60 patients with mild to moderate osteoarthritis of the knee (based on Kellogg's Scor2-3 and maximum VAS (visual analogue scale) of 5) were selected and after completing the informed consent form, they were numbered and divided into three groups of 20 people with the help of computer sorting software.

Settings and conduct

All three groups are treated and examined for 8 weeks: Embedding group A is done with cut-gut thread at different points and in a sterile way. Group B is subjected to TENS high frequency Group C is treated with 400 mg ibuprofen twice a day at home Each of the patients before the start of the treatment (beginning of the first week) and at the end of the intervention (the end of 8 weeks), 5 cc of venous blood from each patient was taken in three 1.5 cc tubes and transferred to the immunology laboratory while maintaining the cold chain and the level of IL-6 It will be reviewed

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Patients diagnosed with knee OA based on ACR 2) Age 50 to 65 years 3) Only one knee is involved 4) Have a VAS pain score of 4 or higher 5) Consent to participate in the study Non-entry criteria: 1) Conflict of 2 knees 1) The surgery has been detailed or is in the process of surgery 2) Knee arthroscopy has been performed in the last year 3) In the last six months, have any therapeutic intervention such as intra-articular injection or acupuncture

Intervention groups

group A, TENS group and group C receive ibuprofen.

Main outcome variables

Changes in the amount of pain; Inflammatory factors;
The amount of physical activity; Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121228011912N7**

Registration date: **2023-10-21, 1402/07/29**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-21, 1402/07/29**

Update count: **0**

Registration date

2023-10-21, 1402/07/29

Registrant information

Name

Hamidreza Bahrami Taghanaki

Name of organization / entity

Mashhad University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

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

Comparison of the effectiveness of three treatment methods, TENS, embedding, acupuncture and drug therapy on the level of interleukin 6 and knee osteoarthritis pain.

Public title

Comparison of the effectiveness , TENS, embedding, acupuncture and drug therapy .

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Treatment with the diagnosis of knee OA based on the criteria of ACR (American College of Rheumatology) Age 50 to 65 years Only one knee is involved Have a VAS pain score of 4 or higher (visual analogue scale) Be literate Consent to participate in the study

Exclusion criteria:

Conflict of 2 knees The surgery has been detailed or is in the process of surgery Knee arthroscopy has been performed in the last year In the last six months, have any therapeutic intervention such as intra-articular injection or acupuncture Having any kind of disease that causes malfunction of the immune system, such as: auto-immune, connective tissue diseases, diabetes, cancer, etc. Have a pacemaker

Age

From **45 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the online site <https://www.sealedenvelope.com> random allocation of three classes are placed in a.b.c groups. Randomization based on block randomization will be done with blocks of 4 and 6. The prepared blocks will be placed in envelopes. One of the envelopes will be randomly selected according to the order of patients' arrival, and patients will be assigned to groups based on the obtained blocks.

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 Mashhad University of Medical Sciences

Street address

Vakilabad, Ferdowsi University campus.

City

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Province

Razavi Khorasan

Postal code

9613885698

Approval date

2023-07-03, 1402/04/12

Ethics committee reference number

IR.MUMS.REC.1402.101

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

Osteoarthritis knee

ICD-10 code

M 17. 9

ICD-10 code description

Gonarthrosis, unspecified

Primary outcomes**1****Description**

Changes in pain

Timepoint

before intervention and weeks 8, 12 and 16

Method of measurement

on the VAS form

2**Description**

Measurement of inflammatory factors: IL-6

Timepoint

before intervention and weeks 8, 12 and 16

Method of measurement

bleeding

Secondary outcomes**1****Description**

Changes in the amount of physical activity

Timepoint

before intervention and weeks 8, 12 and 16

Method of measurement

based on the WOMAC form

2**Description**

Change in quality of life

Timepoint

before intervention and weeks 8, 12 and 16

Method of measurement

questionnaire

Intervention groups**1****Description**

Intervention group: Embedding with cut-gut thread in 6 points in a sterile way. The duration of treatment is 8 weeks.

Category

Treatment - Drugs

2**Description**

Intervention group: 4 times a week and each time for 30 minutes, they are subjected to TENS high frequency by the med device with a frequency of 50-100 Hz by the physiotherapist. The duration of treatment is 8 weeks.

Category

Treatment - Devices

3**Description**

Control group: They are treated with ibuprofen at a dose of 400 mg twice a day at home. The duration of treatment is 8 weeks.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ortopedi

Full name of responsible person

Mohammad nematshahi

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

hamid reza bahrami

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable