Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 ligh 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
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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
Mashhad
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
Osteoartritis 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 ligh 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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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
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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