Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the two techniques of acupuncture stainless steel and gold needle on pain and disability in patient with knee osteoarthritis.

Protocol summary

Study aim
Comparison of the two techniques of acupuncture stainless steel and gold needle on pain and disability in patient with knee osteoarthritis

Design
Randomized , blind clinical trial with three arm parallel groups with 15 patients in each groups .

Settings and conduct
In patient with knee osteoarthritis we do acupuncture at five points in ten session in first group with stainless steel needle , in second group with gold needle and in third group with placebo needle . then we will evaluate the pain score and disability with the WOMAC questionnaire .

Participants/Inclusion and exclusion criteria
Inclusion criteria symptomatic knee osteoarthritis according to American college of Rheumatology criteria. patients with knee injection during the previous 6 month, neurologic or musculoskeletal diseases or history of knee surgery were excluded .

Intervention groups
In patient with knee osteoarthritis we do acupuncture at five point , SP 9, ST 34, ST 35 , ST 36, GB 34 , for 20 minute in ten session in first group with stainless steel needle , in second group with gold needle and in third group with placebo needle .

Main outcome variables
pain score and disability .

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140907019073N3**
Registration date: **2020-02-13, 1398/11/24**
Registration timing: **retrospective**
Last update: **2020-02-13, 1398/11/24**
Update count: **0**

Registration date
2020-02-13, 1398/11/24

Registrant information

Name
Ali Mazaherinezhad

Name of organization / entity
IUMS

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-29, 1398/07/07

Expected recruitment end date
2020-01-27, 1398/11/07

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the two techniques of acupuncture stainless steel and gold needle on pain and disability in patient with knee osteoarthritis.

Public title
Effect of the acupuncture in treatment of knee osteoarthritis.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patient with symptomatic knee osteoarthritis

Exclusion criteria:

use of perednisolone more than 10 mg /d history of knee surgery have knee exercise therapy or physiotherapy in 3 month ago injection in knee joint in 6 month ago patient with any neuroskeletal disease

Age

From **40 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who met the inclusion criteria will be randomly assigned to three groups with computer-assisted block randomization. Each block included 3 groups .

Blinding (investigator's opinion)

Single blinded

Blinding description

Patient and Data Safety and Monitoring Committee. we will use placebo needle that we patch it on the skin without insertion .

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of iran university of medical scirnces

Street address

Hemmat Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1445613131

Approval date

2019-07-22, 1398/04/31

Ethics committee reference number

IR.IUMS.FMD.REC.1398.193

Health conditions studied

1

Description of health condition studied

pain and disability in patient with knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

pain

Timepoint

In the end of intervention - in the 4 weeks- in the 12 weeks

Method of measurement

Visual Analogue Scale score

2

Description

knee function

Timepoint

In the end of intervention - in the 4 weeks- in the 12 weeks

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1 Acupuncture with stainless steel needle for 20 minute at ST 35 , GB 34, ST 36, SP 9, ST 34 points in 10 session.

Category

Treatment - Other

2

Description

Intervention group: 2 Acupuncture with gold needle for 20 minute at ST 35 , GB 34, ST 36, SP 9, ST 34 points in 10 session.

Category

Treatment - Other

3

Description
Control group: attached the needle to the skin with foam pad without penetration of the skin for 20 minute at ST 35 , GB 34, ST 36, SP 9, ST 34 points in 10 session.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram hospital
Full name of responsible person
Ali mazaherinezhad
Street address
Niayesh Ave., Sattar khan St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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Niayesh Ave., Sattarkhan St. tehran
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Ali Mazaherinezhad
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Sport Medicine
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
resident

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Other areas of specialty/work
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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
IPD collection for the primary and secondary outcomes

When the data will become available and for how long
immediately after publication

To whom data/document is available
people working in academic institution

Under which criteria data/document could be used
the result of further analysis may not be presented to public without permission

From where data/document is obtainable
Mazaherinezhad.a@iums.ac.ir

What processes are involved for a request to access data/document
A reasonable request from an academic source will be responded within 10 working days

Comments