

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 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)

Phone

+98 21 6435 2446

Email address

mazaherinezhad.a@iums.ac.ir

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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1458843337

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Ali mazaherinezhad

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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 scientific inquiries

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Elham mousavi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Sport Medicine

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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