Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Investigating and comparing the effect of subcutaneous and intradermal mesotherapy on improving pain and function in patients with osteoarthritis of the knee: a randomized clinical trial study

Protocol summary

Study aim

Investigating and comparing the effect of mesotherapy by two subcutaneous and intradermal methods on improving pain and function of patients with knee osteoarthritis

Design

A parallel randomized single blind clinical trial study in 2023-2024 on 50 patients diagnosed with knee osteoarthritis who were randomly assigned to one of 2 intervention groups.

Settings and conduct

In this single blind study, patients with knee osteoarthritis who referred to physical medicine clinics of Isfahan University of Medical Sciences in 2023-2024 will randomly subjected to intradermal or subcutaneous mesotherapy. After sampling and follow-ups, the analyzer who is unaware of the data, will analyze the data.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with mild to moderate osteoarthritis of the knee based on the Kellgren Lawrence criteria, aged between 40 and 70 years with clinical symptoms at least in the last month; Exclusion criteria: history of knee surgery. Rehabilitation treatments in the last 3 months, presence of any neurological, infectious, cognitive impairment, malignancy, cardiac and renal diseases, pregnancy

Intervention groups

In the first intervention group, 6 sessions of subcutaneous injection of 20 mg of piroxicam with a volume of 1 ml along with 2 ml of lidocaine 2%, 2 sessions per week and for 3 weeks will be performed in 6 aqua puncture points around the knee. In the second intervention group, intradermal injection with drugs, the number of sessions and injection points similar to the first intervention group will be done. The recommendation to follow the correct lifestyle and perform exercises related to strengthening the quadriceps muscle and then stretching the cuff muscles (each time for 20-30 seconds and for 10-20 times a day, depending on the individual's tolerance) will be done in both groups.

Main outcome variables

pain and function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231003059603N1**
Registration date: **2023-10-10, 1402/07/18**
Registration timing: **prospective**

Last update: **2023-10-10, 1402/07/18**
Update count: **0**

Registration date

2023-10-10, 1402/07/18

Registrant information

Name

Maryam Behroozinia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 0048

Email address

maryambehroozynia@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-22, 1402/07/30

Expected recruitment end date
2024-06-19, 1403/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating and comparing the effect of subcutaneous and intradermal mesotherapy on improving pain and function in patients with osteoarthritis of the knee: a randomized clinical trial study

Public title
Investigating and comparing the effect of subcutaneous and intradermal mesotherapy on improving pain and function in patients with osteoarthritis of the knee: a randomized clinical trial study
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with mild to moderate osteoarthritis of the knee based on the Kellgren Lawrence criteria aged between 40 and 70 years clinical symptoms for at least one month.
Exclusion criteria:
Patients who have a history of knee surgery. Patients who have undergone rehabilitation treatments in the last 3 months due to knee pain. Existence of neurological disease, infectious disease, cognitive disorder, malignancy, cardiac and nephrology disease pregnancy
Age
From **40 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **50**
More than 1 sample in each individual
Number of samples in each individual: **2**
If both knees of the patient have osteoarthritis, each knee will be considered as a sample.
Randomization (investigator's opinion)
Randomized
Randomization description
People are placed in 2 groups by random block method. In this way, the first 2 eligible people are selected and after obtaining their consent, they enter to participate in the study. These 2 people are considered as a double block and are sorted according to the last digit of the national code. Treatment methods are Forms A and B are specified and all combinations of 2 are specified
Blinding (investigator's opinion)
Single blinded
Blinding description
The data analyst is unaware of which group each patient was placed in.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Science
Street address
Hezarjerib ave, Isfahan University of Medical Science
City
Isfahan
Province
Isfehan
Postal code
7346181746
Approval date
2023-09-27, 1402/07/05
Ethics committee reference number
IR.ARI.MUI.REC.1402.163

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
pain
Timepoint
before treatment, immediately after last session, one month after treatment
Method of measurement
Visual Analogue Scale questionnaire

2

Description
The degree of knee disability
Timepoint
before treatment, immediately after last session, one

month after treatment

Method of measurement

Western Ontario and McMaster Universities Arthritis Index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 2 sessions per week for 3 weeks, subcutaneous mesotherapy with 1 ml of piroxicam and 2 ml of lidocaine2% in 6 acupuncture points around the knee along with exercise and advice related to lifestyle modification

Category

Treatment - Other

2

Description

Intervention group: 2 sessions per week for 3 weeks, intradermal mesotherapy with 1 ml of piroxicam and 2 ml of 2% lidocaine in 6 acupuncture points around the knee along with exercise and advice related to lifestyle modification

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin hospital

Full name of responsible person

Parisa Taheri

Street address

Sonbulestan Alley, Ibn Sina Street, Shohada Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Parisa Taheri

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

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

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

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

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

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