

# 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**

Isfahan

**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 lidocaine 2% 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

###### **City**

Isfahan

###### **Province**

Isfahan

###### **Postal code**

8148653141

###### **Phone**

+98 31 3112 2020

###### **Email**

Prs\_taheri@yahoo.com

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Gholamreza Asgari

##### **Street address**

Building 4, Hezar Jarib Street, Isfahan University of Medical science

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8174673461

##### **Phone**

+98 31 3668 7898

##### **Email**

askari@mui.ac.ir

##### **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

###### **Street address**

Hezar jarib Street, Isfahan University of Medical Science and health services

###### **City**

Isfahan

###### **Province**

Isfahan

###### **Postal code**

8174673461

###### **Phone**

+98 31 3668 0048

###### **Email**

Prs\_taheri@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Maryam Behroozinia

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

Isfahan university of medical science, Hezarjarib Ave

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0048

**Fax****Email**

maryambehroozynia@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Maryam Behroozinia

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

Isfahan university of medical science, Hezarjarib Ave

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 0048

**Fax****Email**

maryambehroozynia@yahoo.com

## 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