

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

clinical trial comparing the effect of oral piroxicam and subcutaneous injection of piroxicam(mesotherapy) on improvement of pain and function in patients with knee osteoarthritis.

Protocol summary

Summary

target:evaluation of the effectiveness of mesotherapy in decreasing pain and improvement of the function in 40-70y/o patient with knee osteoarthritis.inclusion criteria:mild to moderate disease;exclusion criteria:DM,rheumatic disease,pregnancy,knee injection in recent 3month;sample size:60cases;intervention:subcutaneous injection of 20mg injection in knee in first group and prescription of 20mg of oral piroxicam for 10days in second group and follow up patients For 2 and 4weeks after intervention;time of study:shahrivar 96-khordad 97(september 2017-may2018).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052434113N1**
Registration date: **2017-09-19, 1396/06/28**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-19, 1396/06/28

Registrant information

Name

fahime estakhri

Name of organization / entity

shiraz university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 71 3231 9040

Email address

estakhri@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2017-09-06, 1396/06/15

Expected recruitment end date

2018-06-05, 1397/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

clinical trial comparing the effect of oral piroxicam and subcutaneous injection of piroxicam(mesotherapy) on improvement of pain and function in patients with knee osteoarthritis.

Public title

effectiveness of subcutaneous injection of piroxicam compared with oral use of piroxicam in pain improvement in patients with knee osteoarthritis.

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:40-70y/o patients with mild to moderate osteoarthritis with clinical symptoms at least recent 1month; exclusion criteria:disease such as:DM,collagen vascular and rheumatism,gout,neuropathy,radiculopathy,nerve injury,brucella,BMI>42,trauma ,bleeding tendency,significant hepatic,renal and cardiopulmonaryproblems,knee arthroplasty,allergy to piroxicam,knee injection in recent

3month, pregnancy, cancer, cognitive disorders.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

randomized method: patients with similar sex, age, job, life style and comorbidities put in 2 groups; this study is single blind (blind for information analysts at the end of the study).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

shiraz university of medical sciences

Street address

shiraz, zand street, opposite of felestin street, the central building

City

shiraz

Postal code

71348-14336

Approval date

2016-12-22, 1395/10/02

Ethics committee reference number

IR.SUMS.MED.REC.1395.59

Health conditions studied

1

Description of health condition studied

arthrosis

ICD-10 code

M17.0; M17.

ICD-10 code description

primary gonarthrosis, bilateral; other primary gonarthrosis

Primary outcomes

1

Description

pain improvement

Timepoint

before intervention, 2 and 4 weeks after intervention

Method of measurement

VAS, WOMAC, AXFORD questionnaires

Secondary outcomes

1

Description

improvement in function

Timepoint

before intervention, 2 and 4 weeks after intervention

Method of measurement

VAS, WOMAC, AXFORD questionnaires

Intervention groups

1

Description

group 1 intervention: subcutaneous injection of 20 mg piroxicam with 5 cc lidocaine 2% around knee, repeat 10 days later, life style modification and knee exercise.

Category

Treatment - Drugs

2

Description

group 2 intervention: oral use of 20 mg piroxicam for 10 days, life style modification, exercise for knee.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

hafez hospital

Full name of responsible person

fahime estakhri

Street address

shiraz, bolvare chamran, after social security organization

City

shiraz

2

Recruitment center

Name of recruitment center

rajaee hospital

Full name of responsible person

fahime estakhri
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shiraz chamran near to niyayesh
City
shiraz

+98 71 3235 9317
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estakhrif@sums.ac.ir
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
vice chancellor for research of shiraz university of
medical science
Full name of responsible person
vice chancellor for research of shiraz university of
medical science
Street address
shiraz, zand street ,medical college of shiraz
university

City
shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

vice chancellor for research of shiraz university of
medical science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
shiraz university of medical science
Full name of responsible person
fahime estakhri
Position
physiatry resident
Other areas of specialty/work
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty