Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effects of curcuma, black pepper and ginger on prostaglandin E2 inflammatory marker and pain in patients with knee osteoarthritis in comparison with Naproxen

Protocol summary

Summary

The population under study is affected with chronic knee osteoarthritis and a sample size of 60 patients who are randomly assigned using the numbers table. The study is double-blind that the patient and the analyst will not be aware of the type of intervention. Inclusion criteria: knee idiopathic Osteoarthritis; the age range of 35-75 years; having knee pain with a score of more than 5 according to VAS criteria. Exclusion criteria: having other knee diseases; osteoarthritis of hip or ankle joint; history of physiotherapy and intra-articular injection in the last 6 months; mental illness; neoplasmic tissues of the knee or bleeding; Primary variables: Plasma prostaglandin-2 levels and pain score. Secondary variables: Weight, activity level. The sample size of the two groups is thirty, which will be given to a group of Mixodine extracts and another group of Naproxen drugs for four weeks. The dose for Mixodine is two capsules per day, and Naproxen is two tablets of 250 mg per day.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070511763N32**
Registration date: **2017-10-22, 1396/07/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-10-22, 1396/07/30

Registrant information

Name

Gholamreza Askari

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2017-09-11, 1396/06/20

Expected recruitment end date

2017-10-12, 1396/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of curcuma, black pepper and ginger on prostaglandin E2 inflammatory marker and pain in patients with knee osteoarthritis in comparison with Naproxen

Public title

The effect's of curcuma, black pepper, ginger on inflammatory marker and pain in the patient with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: knee idiopathic Osteoarthritis; in the age range of 35-75 years; walking ability; having knee

pain with a score of more than 5 according to VAS criteria. Exclusion criteria: having other knee diseases; infection of the hip joint and ankle osteoarthritis; radicular pain of lumbar spine disorders; history of physiotherapy and intra-articular injection in the last 6 months; mentall illness; neoplasmic tissues of the knee; infection and bleeding; neurological sensory and motor disorders; history of knee surgery; Obesity; consumption of aspirin and other non-steroidal anti-inflammatory drugs; pregnant women; drug use (such as opium)

Age
From **35 years** old to **75 years** old

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)
Double blinded

Blinding description

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 Sciences

Street address
Hezar Jarib Ave, Isfahan University of Medical Sciences

City
Isfahan

Postal code

Approval date
2017-08-23, 1396/06/01

Ethics committee reference number
IR.MUI.REC.1396.3.422

Health conditions studied

1

Description of health condition studied
Osteoarthritis knee

ICD-10 code
M17

ICD-10 code description
Gonarthrosis [arthrosis of knee]

Primary outcomes

1

Description
E2 prostaglandin plasma level

Timepoint
Before and after intervention

Method of measurement
Kit: Cat.No: ZB-11009S-H9648

2

Description
Pain score

Timepoint
Pre-intervention, first week, second week, third week, forth week

Method of measurement
Womac,vas questionnaire

Secondary outcomes

1

Description
The amount of energy you receive

Timepoint
Before the intervention,the fourth week

Method of measurement
Food recipes questionnaire

2

Description
Weight

Timepoint
Before intervention

Method of measurement
Digital scale

3

Description
Activists level

Timepoint
Before intervention

Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: turmeric extract, black pepper, ginger Myxodine capsule Combination: 300 mg of

curcumin, 5.7 mg of gingernol, 75.3 mg of piperin Dosage: Two capsules per day Time to use: Before meals Duration: four weeks Made in France Holistica Company

Category

Treatment - Drugs

2

Description

Control group: naproxen tablets Dosage: Two 250 mg tablets Usage time: morning and night Duration: four weeks Construction of Iran

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Musa Sadr clinic, Isfahan

Full name of responsible person

Dr. Gholamreza Askari

Street address

Mousavi crossroads, Foroughi Ave, Shohda Sq.

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Doctor Atar Movahdiean Ahmad

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave.

City

Isfahan

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, Isfahan University of Medical Sciences

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

Isfahan University of Medical Sciences

Full name of responsible person

Gorjiyan Pegah

Position

Master nutrition student

Other areas of specialty/work

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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