

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A double blind clinical trial on the effect of saffron tablet on changing level of inflammatory markers Interleukin 1 beta(IL1 β) and Tumor necrosis factor alpha(TNF α) in patients with Knee osteoarthritis

Protocol summary

Summary

The aim of this study was the evaluation of the effect of saffron on the serum levels of inflammatory markers and Knee osteoarthritis disease severity. 80 patients were enrolled to this study with knee osteoarthritis based on ACR criteria with an intensity of 2 to 3 KL radiography grade after obtaining consent. They should have no past history of rheumatologic disease, corticosteroid use, recent trauma within 6 months and chronic kidney disease with a GFR less than 30 ml/min/1.73m². 40 patients were treated with daily 100 mg saffron tablet (active constituents crocin) as intervention group and 40 patients were treated with daily placebo tablet (false color material and starch) as control group, these two groups were studied as double blind, randomized and parallel. At first, WOMAC questionnaire were filled to evaluate the severity of osteoarthritis and blood sample were obtained from patients for studying serum levels of IL 1 beta and TNF alpha, WOMAC questionnaire were filled again to evaluate the severity of osteoarthritis patients in week 6 and 12 (at the end of intervention). Blood samples also were taken of all patients for evaluating level of inflammatory markers at the end of week 12. During study, patients were questioned based on the number of NSAID consumption and visual pain scale by respective collegian per week. Primary outcome of the study were the serum levels of TNF alpha, IL 1 beta and secondary outcome were the severity of osteoarthritis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091029777N1**

Registration date: **2017-03-13, 1395/12/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-13, 1395/12/23

Registrant information

Name

Mona Firouzabadi

Name of organization / entity

Golsestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 17 3242 4377

Email address

firouzabadi@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Golestan University of Medical Science

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A double blind clinical trial on the effect of saffron tablet on changing level of inflammatory markers Interleukin 1 beta(IL1 β) and Tumor necrosis factor alpha(TNF α) in patients with Knee osteoarthritis

Public title

The effect of saffron tablet on the level of inflammatory markers with knee osteoarthritis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Knee osteoarthritis patients based on American College of Rheumatology(ACR) diagnostic criteria with an intensity of 2 to 3 according to Kellgren and Lawrence(KL) radiography grade, Patients with an average age of 50 to 70 years old; Exclusion criteria: Known hypersensitivity to Saffron, Patients with other rheumatologic diseases, Patients with active malignant disease or infection, Patients with known mental illness, Patients with a history of recent Knee surgery and severe trauma(within 6 months), Patients with hip osteoarthritis, Patients with septic arthritis, Patients with active gastrointestinal bleeding or a history of it, Patients with chronic kidney disease when the estimated Glomerular Filtration Rate(GFR) is less than 30 ml/min/1.73m², Severe leukopenia, Patients requiring long term use of corticosteroids such as asthma or inflammatory bowel disease.

Age

From **50 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization will be done using the enclosed envelope.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Golestan University of Medical Science

Street address

4 Kilometer of Gorgan-sari Road, Falsafi educational campus, Vice Chancellor of Technology and Information, Gorgan

City

Gorgan

Postal code

4934174515

Approval date

2016-05-15, 1395/02/26

Ethics committee reference number

IR.GOUMS.REC.1395.22

Health conditions studied

1

Description of health condition studied

Knee Osteoarthritis

ICD-10 code

M17.0

ICD-10 code description

Bilateral primary osteoarthritis of knee

Primary outcomes

1

Description

Serum levels of TNF alpha

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

pg/ml

2

Description

Serum levels of IL 1 beta

Timepoint

Baseline and 12 weeks after intervention

Method of measurement

pg/ml

Secondary outcomes

1

Description

The intensity of osteoarthritis

Timepoint

Baseline and sixth and twelfth weeks

Method of measurement

WOMAC questionnaire

Intervention groups

1

Description

Intervention group: Including daily intake of 100 mg saffron(active constituents crocin) pill for 12 weeks

Category

Treatment - Drugs

2

Description

Control group:Including daily intake of 100 mg placebo saffron(false color material and starch) for 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dezyani Specialty and subspecialty clinics

Full name of responsible person

Nafiseh Abdollahi

Street address

Dezyani Specialty and subspecialty clinics, Beheshti street, Gorgan

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Golestan University of Medical Sciences

Full name of responsible person

Mohsen Saeedi

Street address

4 Kilometer of Gorgan-sari Road, Falsafi educational campus, Vice Chancellor of Technology and Information, Gorgan

City

Gorgan

Grant name

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Grant code / Reference number

--

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

Yes

Title of funding source

Vice chancellor for research, Golestan 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

Golestan University of Medical Science

Full name of responsible person

Mohsen Saeedi

Position

Research and Technology Management

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Golestan University of Medical Sciences

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Mona Firouzabadi

Position

Internal medicine resident

Other areas of specialty/work

Street address

Sayyad shirazi hospital, Sayyad shirazi Boulevard, Gorgan

City

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Monafiroozabadi@gmail.com

Web page address**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