

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Evaluation of Crocina on The Cellular Immune Responses in Osteoarthritis Patients

Protocol summary

Summary

Objectives: The effect of crocina on the production of IL-4, IL-1 β , IL-17, IL-10 and TGF- β ; The effect of crocina on gene expression of transcription factors T-bet, GATA3, FOXP3, ROR-gt; The effect of crocina on number of Th1 and Th2, regulatory T cells and Th17 cells; The effect of crocina on the reduction of pain and joint inflammation. Design: Randomized, Double-blind and Placebo controlled; Study population: OA Patients; Volume: 40 persons; Method: Patients divided into two groups; Crocina tablets prescribed to the first group a tablet 15 mg daily along with the conventional medicines; Placebo tablets prescribed to the second group along with the conventional medicines; Blood sampling done before prescribing drug and four months Later. Major Inclusion Criteria: OA patients aged 40 to 75; The severity of joint damage between grade 2 and 3; Patients with no history of injury; Patients with the Body Mass Index (BMI) less than 30. Major Exclusion Criteria: OA patients aged less than 40 and more than 75; The severity of joint damage in grade 1 and 4; Patients with history of injury and BMI 30 or more. Intervention: Treatment with drug; Prescription of crocina at dose of 15 mg daily; Prescription of placebo at dose of 15 mg daily in the control group. Time: 4 months. Main Outcome Measures: Osteoarthritis, Pain, Inflammation, Crocin, IL-4, IL-1 β , IL-17, IL-10, TGF β , CD127, Gene expression of T-bet; Gene expression of GATA3; Gene expression of FOXP3; Gene expression of RORgt; The number of Th1, Th2, T-regulatory and Th17.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021910507N2**

Registration date: **2016-07-11, 1395/04/21**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-07-11, 1395/04/21

Registrant information

Name

Zhaleh Shariati Sarabi

Name of organization / entity

Department of Internal Medicincine, Imam Reza Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 1802 2370

Email address

shariatij@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2016-07-20, 1395/04/30

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Crocina on The Cellular Immune Responses in Osteoarthritis Patients

Public title

Evaluation of Crocina on The Cellular Immune Responses in Osteoarthritis Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Osteoarthritis patients aged 40 to 75; Patients with the severity of joint damage between grade 2 and grade 3 based on radiographic images; Patients with no history of joint surgery; Patients with no history of injury, no diabetic disorders, no rheumatism, no kidney disease, no osteonecrosis and gout; Patients with no long history of anti-inflammatory drugs consumption; Patients having no insufferable jobs; Patients with the Body Mass Index (BMI) of 30 or less. Exclusion Criteria: Osteoarthritis patients aged less than 40 and more than 75; Patients with the severity of joint damage of the in grade 1 and grade 4 based on radiographic images; Patients with history of joint surgery; Patients with history of injury, diabetic disorders, rheumatism, kidney disease, osteonecrosis and gout; Patients with long history of anti-inflammatory drugs consumption; Patients having insufferable jobs; Patients with a BMI of 30 or more.

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Method of Randomization: 30 Pills of crocina or placebo in quite similar cans, be encoded with Excel Software will be given to the patients completely random; The distributor and the patients will have no knowledge of the contents of the cans; After the end of each month, the patients will receive similar to their previous codes

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Qoreishi Bulding, Daneshgah Street

City

Mashhad

Postal code

91375345

Approval date

2015-12-17, 1394/09/26

Ethics committee reference number

IR.mums.fm.REC.13940279

Health conditions studied

1

Description of health condition studied

Osteoarthritis

ICD-10 code

M15.9

ICD-10 code description

Polyarthrosis, unspecified Generalized osteoarthritis NOS

Primary outcomes

1

Description

Inflammation

Timepoint

Before The Intervention and 4 months after

Method of measurement

Visual

2

Description

Pain

Timepoint

Before The Intervention and 4 months after

Method of measurement

Visual

3

Description

Osteoarthritis

Timepoint

Before The Intervention and 4 months after

Method of measurement

Visualization and gradation 1 to 4

4

Description

Crocin

Timepoint

Four months after the intervention

Method of measurement

International units per millilitre

5

Description

Interleukin-4

Timepoint

Before the intervention and 4 months after

Method of measurement

Picograms per millilitre using ELISA Assay

6

Description

Interleukin-10

Timepoint

Before the intervention and 4 months after

Method of measurement

Picograms per millilitre using ELISA Assay

7

Description

Interleukin-1 β

Timepoint

Before the intervention and 4 months after

Method of measurement

Picograms per millilitre using ELISA Assay

8

Description

TGF- β

Timepoint

Before the intervention and 4 months after

Method of measurement

Picograms per millilitre using ELISA Assay

9

Description

Interleukin-17

Timepoint

Before the intervention and 4 months after

Method of measurement

Picograms per millilitre using ELISA Assay

10

Description

CD127

Timepoint

Before the intervention and 4 months after

Method of measurement

Frequency of desired cells using Flow Cytometry Technique

11

Description

T-bet transcription factor

Timepoint

Before the intervention and 4 months after

Method of measurement

The copy number of desired gene using RT-PCR Assay

12

Description

FOXP3 transcription factor

Timepoint

Before the intervention and 4 months after

Method of measurement

The copy number of desired gene using RT-PCR Assay

13

Description

GATA3 transcription factor

Timepoint

Before the intervention and 4 months after

Method of measurement

The copy number of desired gene using RT-PCR Assay

14

Description

ROR- γ t transcription factor

Timepoint

Before the intervention and 4 months after

Method of measurement

The copy number of desired gene using RT-PCR Assay

15

Description

Regulatory T Cells

Timepoint

Before the intervention and 4 months after

Method of measurement

Frequency of desired cells using Flow Cytometry Technique

16

Description

T helper 1 cells

Timepoint

Before the intervention and 4 months after

Method of measurement

Frequency of desired cells using Flow Cytometry Technique

17

Description

Th17 cells

Timepoint

Before the intervention and 4 months after

Method of measurement

Frequency of desired cells using Flow Cytometry Technique

18

Description

T helper 2 cells

Timepoint

Before the intervention and 4 months after

Method of measurement

Frequency of desired cells using Flow Cytometry Technique

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: Prescription of Crocina drug daily at dose of 15 milligram for 4 months.

Category

Treatment - Drugs

2

Description

Control Group: Prescription of placebo daily at dose of 15 milligram for 4 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr. Zhaleh Shariati Sarabi

Street address

Emam Reza Square, Ebne Sina Avenue

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Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Chancellor, Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Quraishi Building; Daneshgah Street

City

Mashhad

Grant name

931577

Grant code / Reference number

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

Yes

Title of funding source

Research Chancellor, Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Javad Sanchooli

Position

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Other areas of specialty/work

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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