Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of therapeutic and immunologic effects of Crocina in knee osteoarthritis patients: A randomized double-blind placebo-controlled trial

Protocol summary

Study aim
Evaluation of therapeutic and immunologic effects of Crocina in knee osteoarthritis patients

Design
A randomized, blinded controlled clinical trial with a parallel group design of 60 patients

Settings and conduct
This study will be carried out in Bojnurd's medical centers. After preparation of products, the main principal of the study will separate them into identical bottle for weekly consumption and mark them as A, B, C. The orthopedic physician, the patient and the student filling out data are blinded from arms of study. The patient will be asked to consume 1gram acetaminophen four times daily with one of the intervention medications daily for 16 weeks. At first visit, an informed consent form, demographic data, eligibility for enrolling the study, and thhe first blood sample will be collected.In weeks 1, 2, 3, 7, and 16, the patients will be visited and WOMAC, VAS and quality of life checklist will be filled out. The second blood sample will be obtained at week 16 (in total 16 visits).

Participants/Inclusion and exclusion criteria
Inclusion: 1) aged over 40 years 2) Primary osteoarthritis 3) Pain in more than half the days 4) Radiographic evidence 5) A score of 40 from the WOMAC scale as a base 6) No intra-articular injection of hyaluronic acid / glucocorticoid over the last six months 7) Lack of pregnancy Exclusion: 1) intolerance to the drug 2) Do not take medicine properly 3) Serious medical conditions 4) history of liver disease 5) Inability to walk without a cane 6) A history of autoimmune diseases such as rheumatoid arthritis 7) Secondary osteoarthritis, for example, following a trauma

Intervention groups
Patients will be randomized into 3 groups of acetaminophen, with croscina or NSAID, or placebo, randomly divided into permutation blocks (each group 20).

Main outcome variables
Joint range of movement, pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190419043318N1**
Registration date: **2019-07-02, 1398/04/11**
Registration timing: **prospective**

Last update: **2019-07-02, 1398/04/11**
Update count: **0**

Registration date
2019-07-02, 1398/04/11

Registrant information

Name
Adeleh Sahebnasagh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic and immunologic effects of Crocina in knee osteoarthritis patients: A randomized double-blind placebo-controlled trial

Public title

Evaluation of therapeutic effects of Crocina in knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1) aged over 40 years 2) Primary osteoarthritis 3) Pain in more than half the days of the previous month during one of the following activities: walking, climbing and stairs, standing up or sleeping on the bed or mattress during the night 4) Radiographic evidence of tibiafemoral or patellofemoral osteoarthritis 5) A score of 40 from the WOMAC scale as a base 6) No intra-articular injection of hyaluronic acid / glucocorticoid over the last six months 7) The lack of a positive pregnancy test or pregnancy program during the study

Exclusion criteria:

1) intolerance to the drug 2) Do not take medicine properly 3) Serious medical conditions that the patient can not regularly attend periodic visits include severe cardiovascular disease such as angina or heart attack, severe hypertension, recent stroke, insulin dependent diabetes, psychiatric disorders, kidney disease, liver disease, active concen , And anemia 4) history of liver disease 5) Inability to walk without a cane 6) A history of autoimmune diseases such as rheumatoid arthritis 7) Secondary osteoarthritis, for example, following a trauma

Age

From **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The eligible patients who meet the criteria will assigned into one of the intervention groups, by using a permuted block randomization method. Blocks of four will be used. Each prescribed medication will be given a six-digit number by the principal investigator. Patients, treatment team, and the investigator of clinical responses will not be aware of the types of interventions. At the end of the study, the principal investigator will decode the numbered consumed medications and assigne each to the appropriate group correctly.

Blinding (investigator's opinion)

Double blinded

Blinding description

Each prescribed medication will be given a six-digit number by the principal investigator. At the end of the study, the principal investigator will decode the numbered consumed medications and assigne each to the appropriate group correctly. The orthopedic physician, participated patients, and the medical student who is responsible for collecting data and filling out the questionnaire will be blinded to the intervention groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of North Khorasan University of Medical Sciences

Street address

Street Shahriar

City

Bojnurd

Province

North Khorasan

Postal code

74877-94149

Approval date

2019-02-24, 1397/12/05

Ethics committee reference number

IR.NKUMS.REC.1397.125

Health conditions studied

1

Description of health condition studied

osteoarthritis

ICD-10 code

M19.0

ICD-10 code description

Primary osteoarthritis of other joints

Primary outcomes

1

Description

Joint range of movement

Timepoint

Weeks 1,2,3,7,16

Method of measurement

Clinical examination

2

Description

pain

Timepoint

Weeks 1,2,3,7,16

Method of measurement

VAS, KOOS and WOMAC questionnaire

Secondary outcomes

1

Description

Change in serum levels of inflammatory mediators (IL-1, INF-γ)

Timepoint

Weeks of 1 and 16

Method of measurement

ELISA Kits

2

Description

Change in serum levels of inflammatory and anti-inflammatory mediators(IL-10)

Timepoint

Weeks of 1 and 16

Method of measurement

ELISA Kits

Intervention groups

1

Description

Intervention group: Acetaminophen tablet 4 times a day plus NSAIDs with one glass of water (one of the following NSAIDs will be considered: 1200mg Ibuprofen, 75mg Indomethacin, 500mg Naproxen, 10mg Piroxicam, 75mg Diclofenac) for 16 weeks

Category

Treatment - Drugs

2

Description

Control group: Acetaminophen tablet 4 times a day plus placebo tablet daily with one glass of water (identical appearance to Crocina tablets, prepared from Pooyesh Sina company) for 16 weeks

Category

Treatment - Drugs

3

Description

Intervention group: Acetaminophen tablet 4 times a day plus Crocina tablet daily with one glass of water (identical appearance to placebo tablets, prepared from Pooyesh Sina company) for 16 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital

Full name of responsible person

Adeleh Sahebnasagh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bojnourd 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
Bojnourd University of Medical Sciences
Full name of responsible person
Adeleh Sahebnasagh
Position
Assistant Professor
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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