

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

the effect of crocin on fasting blood sugar, lipid profile, inflammatory cytokines, pro-oxidants-antioxidants balance, depression and anxiety in the patients with metabolic syndrome

Protocol summary

Summary

The purpose of this study is to evaluate the effectiveness of crocin in patients with metabolic disorders. This is a 8-week randomized and double-blind placebo controlled clinical trial. Sixty adult patients who will be diagnosed with early stage metabolic syndrome based on AHA 2009 guidelines will be randomly assigned into crocin (15 mg/BID) or control (placebo/BID) group. At the first visit for intervention study and end of treatment course, a blood sample will be drawn and the following factors will be measured; lipid profile (LDL, TG, TC, HDL level), fasting blood sugar (FBS), inflammatory cytokines, including TNF- α , VEGF, EGF, INF- γ , and IL1- α , IL1- β , IL2, IL4, IL6, IL8, IL10, MCP-I and antibody HSP27 , pro-oxidants- antioxidants balance (PAB) and genetic and novel biomarkers of cardio - vascular disorders. In addition, the effect of crocin on the depression and anxiety of the subjects will be investigated. The crocin tablets contain 15 mg crocin (active ingredient), and Lactose and Avicel (as excipients). placebo has no crocin. The tablets are administered orally twice daily for eight weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013080514279N1**
Registration date: **2015-02-01, 1393/11/12**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-01, 1393/11/12

Registrant information

Name

Mojtaba Foroutan Tanha

Name of organization / entity

Medical University of Mashhad

Country

Iran (Islamic Republic of)

Phone

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Email address

foroutantm851@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Council of Mashhad University of Medical Sciences

Expected recruitment start date

2014-04-06, 1393/01/17

Expected recruitment end date

2014-06-28, 1393/04/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of crocin on fasting blood sugar, lipid profile, inflammatory cytokines, pro-oxidants-antioxidants balance, depression and anxiety in the patients with metabolic syndrome

Public title

the effect of crocin on patients with metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the desire to participate in the study;

having no previous history of angiography; having no order of emergency angiography; having 20 number anxiety; age over 18 years old;; health in the legs and hands; patients not taking the narcotic drug alcohol, ; having no previous history of mental disorder; not using anticoagulation medications; No diabetes; Do not have the risk of deep vein thrombosis. Exclusion criteria: injury or infection at the site of reflex zone therapy; anxiolytic or hypnotic drugs in the 8 hours before reflex zone therapy; condition of hemodynamic is unstable; transfer of patient to intensive care unit and cardiopulmonary resuscitation of the patient

Age

From **18 years** old

Gender

Both

Phase

1

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**

Used

Assignment

Parallel

Other design features

The subjects who entered the trial, chose a numbered sealed envelope containing the randomized allocation to the intervention or control group. All subjects gave written informed consent before beginning the study.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Regional Committee for Ethics in Research,
Mashhad University of Medical Sciences

Street address

Qureshi Building, Daneshagh Street

City

Mashhad

Postal code**Approval date**

2013-11-02, 1392/08/11

Ethics committee reference number

920782

Health conditions studied**1****Description of health condition studied**

Metabolic syndrome

ICD-10 code

E88.81

ICD-10 code description

Metabolic syndrome

Primary outcomes**1****Description**

Lipid profiles

Timepoint

Before the intervention, and 8 weeks after the intervention

Method of measurement

Laboratory analysis of the blood samples taken before the intervention and 8 weeks after the commencement of the intervention

2**Description**

inflammatory cytokines

Timepoint

Before the intervention, and 8 weeks after the intervention

Method of measurement

Laboratory analysis of the blood samples taken before the intervention and 8 weeks after the commencement of the intervention

3**Description**

Fast blood sugar (FBS)

Timepoint

Before the intervention, and 8 weeks after the intervention

Method of measurement

Laboratory analysis of the blood samples taken before the intervention and 8 weeks after the commencement of the intervention

4**Description**

pro-oxidants- antioxidants balance (PAB)

Timepoint

Before the intervention, and 8 weeks after the intervention

Method of measurement

Laboratory analysis of the blood samples taken before the intervention and 8 weeks after the commencement of the intervention

5

Description

depression and anxiety

Timepoint

Before the intervention, and 8 weeks after the intervention

Method of measurement

Analysis of the questionnaires filled before the intervention and 8 weeks after the commencement of the intervention

6

Description

Antibody HSP27

Timepoint

Before the intervention, and 8 weeks after the intervention

Method of measurement

Laboratory analysis of the blood samples taken before the intervention and 8 weeks after the commencement of the intervention

Secondary outcomes

empty

Intervention groups

1

Description

Patients in the intervention group receive 2 oral pills/day containing 15 mg of crocin for 8 consecutive weeks. Crocin is a carotenoid, which is isolated and purified from the extract of saffron.

Category

Treatment - Drugs

2

Description

Patients in the control group receive 2 oral placebo pills/day for consecutive 8 weeks. placebo has no crocin and look like the crocin tablets.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Street address

Shariati Square, Ahmadabad Street

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Council of Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

School of Pharmacy, Mashhad University of Medical Sciences, Azadi Square

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Council of 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

Mohammad Matin Khademi

Position

Pharmacy student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Mashhad University of Medical Sciences

Full name of responsible person

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Position

PhD

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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

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mojtaba Foroutan Tanha

Position

Pharmacy student