Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effects of Crocin supplementation on metabolic parameters, systemic inflammation and AMP- activated protein kinase, TNF-α and NF-Kβ in patients with type 2 diabetes.

Protocol summary

Study aim

The aim of this double-blind randomized clinical trial is to determine the effects of Crocin supplementation on metabolic parameters, systemic inflammation and AMP-activated protein kinase, Tumor Necrosis Factore-α and Nuclear Factor-Kappa β in patients with type 2 diabetes (T2DM).

Design

This study is a double-blind, randomized controlled clinical trial with two parallel groups. 50 patients will be randomly assigned into Crocin and control group.

Settings and conduct

Patients with type 2 diabetes referring to the Diabetes Clinic of Imam-Hossein Hospital will be invited to participate. After assessing the entrance criteria, 10 cc blood samples are taken. The food recall and physical activity questionnaire is completed. Anthropometric measurements and blood pressure are taken. Supplements are given to patients for a month. For double-blind implementation(patients and investigators), all boxes of supplements by a third party is coded as A and B.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged 30-70 years old; Body mass index 18.5-30; clinical diagnosis of T2DM (for at least one year); Non-inclusion criteria: having liver, kidney, inflammatory and pulmonary diseases; alcohol-drug abuse; pregnancy and lactation; insulin injection.

Intervention groups

Intervention group :Crocin tablet; Control group: placebo tablet. Patients in the Crocin group will receive, for 12 weeks, two tablets of Crocina (Samisaz Company) per day, each containing 15 mg of Crocin. Patients in the control group will receive 2 tablets of placebo containing starch per day.

Main outcome variables

Serum concentrations of Glucose; Insulin; Insulin resistance index (HOMA-IR); Lipid profile; malondialdehyde; Total oxidant capacity; Total anti-oxidant capacity; High sensitivity c-reactive protein; Hemoglobin A1C levels; Interlukin-6; nuclear factor kappa-B; Tumor necrosis factor-a; AMPK.

General information

Reason for update

End of the intervention date

Acronym

IRCT registration information

IRCT registration number: **IRCT20170408033308N2**
Registration date: **2019-08-13, 1398/05/22**
Registration timing: **retrospective**

Last update: **2020-06-13, 1399/03/24**
Update count: **1**

Registration date

2019-08-13, 1398/05/22

Registrant information

Name

Vahideh behrouz

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-18, 1397/11/29

Expected recruitment end date
2019-05-22, 1398/03/01
Actual recruitment start date
2019-02-18, 1397/11/29
Actual recruitment end date
2019-06-19, 1398/03/29
Trial completion date
2019-06-19, 1398/03/29

Scientific title
The effects of Crocin supplementation on metabolic parameters, systemic inflammation and AMP- activated protein kinase, TNF-α and NF-Kβ in patients with type 2 diabetes.

Public title
Effects of Crocin in Treatment of Diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Aged 30-70 years old Clinical diagnosis of type 2 diabetes (for at least 1 year) Body mass index (BMI) 18.5-30 kg/m2
Exclusion criteria:
Having liver, kidney, inflammatory and pulmonary diseases; Alcohol-drug abuse; Pregnancy and lactation; Insulin injection.
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**
Actual sample size reached: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients on the basis of age and sex are categorized and are randomly assigned to the Crocin or placebo group. To random allocation, a Stratified Blocked Randomization method is used. After specifying blocks of size 4 and allocating numbers to each block, a random number table is used to determine the treatment assignment list. Randomization is concealed in sequentially numbered, sealed, opaque envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a double-blind (investigators and patients) trial. For double-blind implementation, at the beginning of the study, all boxes containing crocin or placebo by a third party (someone other than the researchers) is coded as A and B.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti medical university
Street address
No. 46, West Arghavan St., Farahzadi Blv., Shahrak Qods,
City
Tehran
Province
Tehran
Postal code
1981619573
Approval date
2019-02-17, 1397/11/28
Ethics committee reference number
IR.SBMU.nnftri.Rec.1398.009

Health conditions studied

1

Description of health condition studied
Patients with type 2 diabetes
ICD-10 code
E08
ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Fasting blood sugar
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Enzymatic assay kit

2

Description
Serum concentrations of insulin
Timepoint
Before the intervention and 12 weeks after the intervention

Method of measurement
The enzyme-linked immunosorbent assay (ELISA)

3

Description
Hemoglobin A1C levels
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Enzymatic assay kit

4

Description
Serum concentrations of malondialdehyde (MDA)
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kit

5

Description
Concentrations of nuclear factor kappa-B in peripheral blood mononuclear cells
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
The enzyme-linked immunosorbent assay (ELISA)

6

Description
Serum concentrations of high sensitivity c-reactive protein (hs-CRP)
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
The enzyme-linked immunosorbent assay (ELISA)

7

Description
Serum concentration of Interleukin 6
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kit

8

Description
Concentrations of tumor necrosis factor alpha in peripheral blood mononuclear cells
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kit

9

Description
Concentrations of AMP-activated protein kinase in peripheral blood mononuclear cells
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) kit

10

Description
Serum concentrations of triglyceride
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Enzymatic assay kit

11

Description
Serum concentrations of total cholesterol
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Enzymatic assay kit

12

Description
Serum concentrations of High-density lipoprotein cholesterol (HDL-C)
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Enzymatic assay kit

13

Description
Serum concentrations of Low-density lipoprotein cholesterol (LDL-C)
Timepoint
Before the intervention and 12 weeks after the intervention
Method of measurement
Enzymatic assay kit

Secondary outcomes

1

Description
Serum concentration of Total oxidant capacity (TOC)
Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

The enzyme-linked immunosorbent assay (ELISA)

2

Description

Serum concentration of Total anti-oxidant capacity (TAC)

Timepoint

Before the intervention and 12 weeks after the intervention

Method of measurement

The enzyme-linked immunosorbent assay (ELISA)

Intervention groups

1

Description

Intervention group: Crocin supplementation: they will receive, for 12 weeks, two tablets of Crocina (Samisaz Company) per day, each containing 15 mg of crocin.

Category

Treatment - Other

2

Description

Control group: they will receive 2 tablets of placebo containing starch (Samisaz Company) per day for 12 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Dr. Meghdad Sedaghat

Street address

Emam Hossein Hosp. - Madani St.

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Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Esmat Naseri

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vahideh Behrouz

Position

Ph.D candidate

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Ph.D Candidate

Latest degree
Master

Other areas of specialty/work
Nutrition

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No. 46, West Arghavan St., Farahzadi Blv., Shahrak Qods

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vahideh.behrouz@gmail.com

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
Not applicable

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
Not applicable

Data Dictionary
Not applicable