

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The effects of Crocin supplementation on metabolic parameters, systemic inflammation and AMP- activated protein kinase, TNF- $\alpha$ and NF-K $\beta$ 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 Factor- $\alpha$  and Nuclear Factor-Kappa  $\beta$  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)

##### Phone

+98 34 3251 0380

##### Email address

vh.behrouz@sbmu.ac.ir

##### 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- $\alpha$  and NF-K $\beta$  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/m<sup>2</sup>

**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.

**City**

Tehran

**Province**

Tehran

**Postal code**

7742595633

**Phone**

+98 21 7343 0045

**Email**

info@ehmc.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Esmat Naseri

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1981619573

**Phone**

+98 21 2207 7425

**Email**

Nasseri\_esm@yahoo.com

**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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1981619573

**Phone**

+98 21 2207 7424

**Email**

Vahideh.behrouz@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Golbon Sohrab

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1981619573

**Phone**

+98 21 2207 7424

**Email**

golbonsohrab@yahoo.com

## Person responsible for updating data

### 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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1981619573

**Phone**

+98 21 2207 7424

**Email**

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