# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparison of the effects of saffron (Crocus Sativus L.), Berberis vulgaris fruit extract, and placebo on components of metabolic syndrome in patients with metabolic syndrome

## Protocol summary


**Summary**

The aim of this double-blind study was to investigate the effects of Berberis vulgaris fruit extract, saffron (Crocus Sativus L.) and placebo on metabolic syndrome. The population in this third-phase clinical trial included all patients referred to cardiac outpatient clinic of Birjand University of Medical Sciences. A total of 90 patients who were diagnosed with metabolic syndrome, aged between 30 and 60 years, and were willing to participate in the study were randomly selected and allocated into three groups through simple randomization method. A total of 30 patients were allocated into the saffron group, 30 into barberry group, and 30 into the placebo group. The saffron group received on a daily basis a tablet of 100 mg of crocin (constituent of saffron) on a daily basis for three weeks. The barberry group received three 550 mg tablets of Berberis vulgaris fruit extract (an aqueous extract) per day for three weeks. The placebo group received starch tablets, similar in appearance to tablets in other groups, one per day for three weeks. Metabolic syndrome variables, i.e., body mass index, blood pressure, fat distribution pattern, fasting blood sugar, serum lipid level, triglycerid, total cholesterol, and low and high density lipoprotein were measured at baseline and at the end of interventions.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2016112617756N11**
Registration date: **2017-01-02, 1395/10/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2017-01-02, 1395/10/13


**Registrant information**

**Name**
Mohammad Bagher Roozgar
**Name of organization / entity**
Birjand University of Medical Sciences
**Country**
Iran (Islamic Republic of)
**Phone**
+98 56 3239 5680
**Email address**
mbroozgar@bums.ac.ir


**Recruitment status**

**Recruitment complete**


**Funding source**

Birjand University of Medical Sciences


**Expected recruitment start date**

2007-03-21, 1386/01/01

**Expected recruitment end date**

2008-03-20, 1387/01/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effects of saffron (Crocus Sativus L.), Berberis vulgaris fruit extract, and placebo on components of metabolic syndrome in patients with metabolic syndrome

**Public title**

Effects of saffron and barberry on components of metabolic syndrome

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: age between 30 and 60 years; individuals with metabolic syndrome defined by the Adult Treatment Panel III (ATP III); provision of informed consent; absence of any history of major cardiac, pulmonary, hepatic, gastroenterological, neurologic, psychiatric, or renal disease; non-pregnancy; Exclusion criterion: Unwillingness to continue participation

**Age**

From **30 years** old to **60 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

This study was double-blinded such that neither the participant was aware to which group s/he belonged nor the researcher was aware which particular participant belonged to which group under study. Furthermore, the ethical code of the study is 02-02-87. It is because prior to the year 2015, ethical codes were issued based on, and in the format of, the date the Ethics Committee's meeting was held to proceed the research project.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Birjand University of Medical Sciences

**Street address**

Birjand University of Medical Sciences, Ghaffari St.,

**City**

Birjand,

**Postal code**

**Approval date**

2008-04-21, 1387/02/02

**Ethics committee reference number**

02-02-87

## Health conditions studied

### 1

**Description of health condition studied**

Metabolic disorder

**ICD-10 code**

E88

**ICD-10 code description**

Other metabolic disorders

## Primary outcomes

### 1

**Description**

Body Mass Index

**Timepoint**

Before intervention and three weeks after intervention

**Method of measurement**

a Seca 200 scale with attached stadiometer

### 2

**Description**

hypertension

**Timepoint**

Before intervention and three weeks after intervention

**Method of measurement**

mercury sphygmomanometer

### 3

**Description**

fasting blood sugar (FBS)

**Timepoint**

Before intervention and three weeks after intervention

**Method of measurement**

ParsAzmun kit

### 4

**Description**

triglyceride (TG)

**Timepoint**

Before intervention and three weeks after intervention

**Method of measurement**

ParsAzmun Kit

### 5

**Description**

total cholesterol (Chol)

**Timepoint**

Before intervention and three weeks after intervention

**Method of measurement**

ParsAzmun Kit

### 6

**Description**

low- and high-density lipoprotein (LDL and HDL)

**Timepoint**

Before intervention and three weeks after intervention

**Method of measurement**

ParsAzmun Kit

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

The first intervention group (saffron group): tablets of 100 mg of crocin (constituent of saffron) one per day for 3 weeks

**Category**

Treatment - Drugs

### 2

**Description**

The second intervention group (barberry group): three tablets of 550 mg Berberis vulgaris fruits extract per day for three weeks

**Category**

Treatment - Drugs

### 3

**Description**

The placebo group: starch tablets one per day for three weeks

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

cardiac outpatient clinic of Birjand University of Medical Sciences

**Full name of responsible person**

Dr Tooba Kazemi

**Street address**

Vali-Asr Hospital, Ghaffari St.,

**City**

Birjand,

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice-chancellor for Research, Birjand University of Medical Sciences

**Full name of responsible person**

Dr Tooba Kazemi

**Street address**

Ghaffari St.,

**City**

Birjand,

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice-chancellor for Research, Birjand 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**

Birjand University of Medical Sciences

**Full name of responsible person**

Dr Tooba Kazemi

**Position**

Vice-chancellor for Research and Technology

**Other areas of specialty/work**

**Street address**

Ghaffari St.,

**City**

Birjand,

**Postal code**

**Phone**

+98 56 3239 1200

**Fax**

**Email**

drtooba.kazemi@gmail.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Dr Tooba Kazemi

**Position**

Full Professor

**Other areas of specialty/work**

**Street address**

Ghaffari St.,

**City**

Birjand,

**Postal code**

9717853577

**Phone**
+98 56 3239 1200
**Fax**
**Email**
drtooba.kazemi@gmail.com
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Birjand University of Medical Sciences
**Full name of responsible person**
Mohammad Bagher Roozgar
**Position**
PhD Candidate in Translation Studies
**Other areas of specialty/work**
**Street address**
Ghaffari St.,
**City**
Birjand,
**Postal code**
9717853577
**Phone**
+98 56 3239 5680
**Fax**
**Email**
mbroozgar@bums.ac.ir
**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*