

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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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

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Full Professor

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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**

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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