Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 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