

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The Effects of Saffron Supplementation on Oxidative Indices in Patients with Metabolic Syndrome

Protocol summary

Study aim

The Effects of Saffron Supplementation on Oxidative Indices in Patients with Metabolic Syndrome

Design

The current study is a randomized, double-blind, placebo-controlled clinical trial with parallel groups. A total of 106 subjects were enrolled between September 2010 and March 2011.

Settings and conduct

Patients with metabolic syndrome who referred to Nutrition Clinic of the Ghaem Hospital were enrolled in the study. All volunteers, care providers and statistician were blinded after assignment to intervention. So that, the capsules containers were coded as A and B by a non-researcher person and remained confidential until data analysis. The placebo capsules were similar to the drugs regarding the weight and color.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-75 years old, Patients with Metabolic Syndrome according to the International Diabetic Federation criteria; Exclusion criteria: Systemic diseases such as lupus, kidney disease, acquired immunodeficiency syndrome and rheumatoid arthritis, Pregnant and lactating women, Drug usage including consumption of the lipid-lowering, antihypertensive and antidiabetic drugs

Intervention groups

1) Drug: a group receiving Barberry capsules (100 mg/day) for 12 weeks, 2) Placebo: the control group who taking a placebo capsule for a period of 12 weeks.

Main outcome variables

Anti-HSP titre; Pro-Oxidant-Antioxidant Balance; Superoxide Dismutase

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110726007117N10**

Registration date: **2020-03-29, 1399/01/10**

Registration timing: **retrospective**

Last update: **2020-03-29, 1399/01/10**

Update count: **0**

Registration date

2020-03-29, 1399/01/10

Registrant information

Name

Majid Ghayour Mobarhan

Name of organization / entity

Mashhad University of Medical Sciences,

Country

Iran (Islamic Republic of)

Phone

+98 51 1822 8573

Email address

ghayourm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-02-20, 1389/12/01

Actual recruitment start date

2010-09-01, 1389/06/10

Actual recruitment end date

2011-03-30, 1390/01/10

Trial completion date

2011-03-30, 1390/01/10

Scientific title

The Effects of Saffron Supplementation on Oxidative Indices in Patients with Metabolic Syndrome

Public title

Effect of Saffron in Metabolic Syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
18–75 years old Patients with Metabolic Syndrome according to the International Diabetic Federation criteria
Exclusion criteria:
Systemic diseases such as lupus, kidney disease, acquired immunodeficiency syndrome and rheumatoid arthritis Pregnant and lactating women Drug usage including consumption of the lipid-lowering, antihypertensive and antidiabetic drugs

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **30**
Actual sample size reached: **35**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization: The random allocation sequence was made using the computer randomization method. Sequentially numbered sealed envelopes were used to concealment the random allocation sequence which opened by a person not involved in the project.

Blinding (investigator's opinion)
Double blinded

Blinding description
The participants, care providers and statistician were blinded after assignment to intervention. So that, the capsules bottles were coded by a non-researcher person and remained confidential until data analysis. Moreover, the placebo capsules were similar to the Saffron ones concerning the shape, weight and color.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical

Sciences
Street address
Faculty of Medicine, Azadi Square, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
99199-91766
Approval date
2009-11-04, 1388/08/13
Ethics committee reference number
87480

Health conditions studied

1

Description of health condition studied

Metabolic Syndrome

ICD-10 code

E88.81

ICD-10 code description

Metabolic syndrome

Primary outcomes

1

Description

Anti-Heat Shock Protein titre

Timepoint

Before the intervention and 12 weeks after taking drug or placebo

Method of measurement

Enzyme Linked Immunosorbent Assay

2

Description

Pro-Oxidant-Antioxidant Balance

Timepoint

Before the intervention and 12 weeks after taking drug or placebo

Method of measurement

Enzyme Linked Immunosorbent Assay

3

Description

Superoxide Dismutase

Timepoint

Before the intervention and 12 weeks after taking drug or placebo

Method of measurement

Spectrophotometry

Secondary outcomes

1

Description

Serum Copper
Timepoint
Before the intervention and 12 weeks after taking drug or placebo
Method of measurement
Atomic Absorption

2

Description
Serum Zinc
Timepoint
Before the intervention and 12 weeks after taking drug or placebo
Method of measurement
Atomic Absorption

Intervention groups

1

Description
Intervention group: Subjects in the intervention group receive Barberry capsules (daily intake of 100 mg) for 12 weeks (n=35). The participants take 2 capsule 50 mg every day, which was contained in an unlabeled bottle. Capsules are from Novin Saffron company (Mashhad, Iran).
Category
Treatment - Drugs

2

Description
Control group: Control group: Placebo capsules are prepared by a similar company and are similar to the Saffron capsules regarding the color, shape and size. The control group receive a placebo capsule for a period of 12 weeks. The participants take 2 capsule 50 mg every day, which was contained in an unlabeled bottle. Capsules are from Novin Saffron company (Mashhad, Iran).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Majid Ghayour-Mobarhan
Street address
Ahmadabad
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99199-91766

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+98 51 3840 0001
Fax
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b.ghaem@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayour-Mobarhan
Street address
Faculty of Medicine, Azadi Square
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+98 51 3800 2287
Email
ghayourm@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayour-Mobarhan
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Nutrition

Street address

Nutrition Department, Faculty of Medicine, Azadi
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Majid Ghayour- Mobarhan

Position

Associate professor

Latest degree

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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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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Raw data will be shared upon a reasonable request from
the corresponding author.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Following a reasonable request, deidentified data will be
shared.

When the data will become available and for how long

After publication of paper(s) upon a reasonable request

To whom data/document is available

Study PI and executive team

Under which criteria data/document could be used

For reasonable research or clinical purpose

From where data/document is obtainable

Dr Majid Ghayour-Mobarhan

What processes are involved for a request to access data/document

Direct e-mail

Comments