

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effects of Barberry Supplementation on Oxidative Indices in Patients with Metabolic Syndrome: A Randomized Double Blind Clinical Trial

Protocol summary

Study aim

The Effects of Barberry 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 November 2013 and March 2014.

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: 18–65 years old, Patients with Metabolic Syndrome according to the International Diabetic Federation criteria; Exclusion criteria: Systemic diseases, 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 (600 mg/day) for 6 weeks, 2) Placebo: the control group who taking a placebo capsule for a period of 6 weeks.

Main outcome variables

Anti-Heat Shock Protein titre; Pro-Oxidant–Antioxidant Balance; Superoxide Dismutase

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110726007117N9**

Registration date: **2020-03-25, 1399/01/06**

Registration timing: **retrospective**

Last update: **2020-03-25, 1399/01/06**

Update count: **0**

Registration date

2020-03-25, 1399/01/06

Registrant information

Name

Majid Ghayour Mobarhan

Name of organization / entity

Mashhad University of Medical Sciences,

Country

Iran (Islamic Republic of)

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+98 51 1822 8573

Email address

ghayourm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2013-11-26, 1392/09/05

Expected recruitment end date

2014-03-02, 1392/12/11

Actual recruitment start date

2013-11-26, 1392/09/05

Actual recruitment end date

2014-03-02, 1392/12/11

Trial completion date

2014-03-02, 1392/12/11

Scientific title

The Effects of Barberry Supplementation on Oxidative Indices in Patients with Metabolic Syndrome: A Randomized Double Blind Clinical Trial

Public title

The Effects of Barberry on Metabolic Syndrome

Treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
18–65 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 **65 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **40**
Actual sample size reached: **53**

Randomization (investigator's opinion)
Randomized

Randomization description
The random allocation sequence was made using the computer randomization method. Sequentially numbered sealed envelopes were used to implement the random allocation sequence which opened by a person not involved in the project. 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 Barberry ones concerning the shape, weight and color.

Blinding (investigator's opinion)
Double blinded

Blinding description
All subjects, 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 statistical analysis. The placebo capsules were similar to the drugs regarding the 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

Azadi Square, Faculty of Medicine

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 6 weeks after taking drug or placebo

Method of measurement

Enzyme Linked Immunosorbent Assay

2

Description

Pro-Oxidant-Antioxidant Balance

Timepoint

Before the intervention and 6 weeks after taking drug or placebo

Method of measurement

Enzyme Linked Immunosorbent Assay

3

Description

Superoxide Dismutase

Timepoint

Before the intervention and 6 weeks after taking drug or placebo

Method of measurement

Spectrophotometry

Secondary outcomes

1

Description

Serum Copper

Timepoint

Before the intervention and 6 weeks after taking drug or placebo

Method of measurement

Atomic Absorption

2

Description

Serum Zinc

Timepoint

Before the intervention and 6 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 600 mg) for 6 weeks (n=53). The participants take one capsule every day, which was contained in an unlabeled bottle. Capsules are from Khoosheh Sorkhe Shargh Agro Industrial company (Tehran, Iran).

Category

Treatment - Drugs

2

Description

Control group: Placebo capsules are prepared by a similar company and are similar to the Barberry capsules regarding the color, shape and size. The control group receive a placebo capsule for a period of 6 weeks. The participants take one capsule every day, which was contained in an unlabeled bottle. Capsules are from Khoosheh Sorkhe Shargh Agro Industrial company (Tehran, Iran).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Nutrition Clinic of the Ghaem Hospital

Full name of responsible person

Majid Ghyour-Mobarhan

Street address

Dr Shariati Square, Ahmadabad Street, Ghaem Hospital, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

Professor
Latest degree
Specialist
Other areas of specialty/work
Nutrition
Street address
Nutrition Department, Faculty of Medicine, Mashhad
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

No more information

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

No - There is not 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

After a reasonable request, deidentified data can 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 Mjid Ghayour Mobarhan

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

Direct email

Comments