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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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 Ghyaour-Mobarhan
Street address
Dr Shariati Square, Ahmadabad Street, Ghaem Hospital, Mashhad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Faculty of Medicine, Mashhad University of Medical Sciences, Azadi Square
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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

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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