

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Comparison of the effect of powdered *Berberis vulgaris* and placebo consumption on flow mediated dilation and vascular inflammatory biomarkers in hypertensive subjects

#### Protocol summary

##### Study aim

The effect of powdered *Berberis vulgaris* consumption on flow mediated dilation and vascular inflammatory biomarkers in hypertensive subjects

##### Design

A single center, randomized, not blinded, controlled clinical trial with a parallel group design and 78 participants

##### Settings and conduct

Seventy six patients with previous history of hypertension and at least one cardiovascular risk factor, referred to Rajaei hospital, will be randomized into two groups, barberry powder (10 g per day) or placebo (10 g) for 8 weeks. Flow mediated dilation and plasma levels of ICAM and VCAM are measured at baseline and after 8 weeks. Patients did not know the type of intervention and the study was single blind.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Willingness to participate in the study; Age between 20-65 years; Having elevated BP (129/ < 85) and known hypertensive patients on medical treatment; At least one other classical cardiovascular disease risk factors, including hyperlipidemia or diabetes mellitus. Exclusion Criteria: Unwillingness to continue participation; BMI > 30; Patients on nitrates; High doses of statins consumption (Atorvastatin > 40 mg/day or Rosuvastatin > 20 mg/day); Consumption of vitamins or minerals supplements during past month; Chronic kidney disease stage 4 or 5.

##### Intervention groups

Intervention group: receiving 10 g of barberry powder for 8 weeks. Control group: receiving 10 g placebo powder containing maltodextrin, citric acid and oral red for 8 weeks.

##### Main outcome variables

Flow mediated dilation (FMD); ICAM and VCAM inflammatory factors

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160702028742N8**

Registration date: **2020-03-20, 1399/01/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-03-20, 1399/01/01**

Update count: **0**

##### Registration date

2020-03-20, 1399/01/01

##### Registrant information

##### Name

Javad Nasrollahzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2236 0656

##### Email address

jnasrolah@razi.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-21, 1398/11/01

##### Expected recruitment end date

2020-05-21, 1399/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the effect of powdered Berberis vulgaris and placebo consumption on flow mediated dilation and vascular inflammatory biomarkers in hypertensive subjects

## Public title

Effect of powdered Berberis vulgaris on vascular function

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Willingness to participate in the study Age between 20-65 years Having elevated blood pressure (129/ < 85) or known hypertensive patients on medical treatment At least one other classical cardiovascular disease risk factors, including hyperlipidemia or diabetes mellitus

### Exclusion criteria:

BMI > 30 Patients on nitrate drugs High doses of statins consumption (Atorvastatin > 40 mg/day or Rosuvastatin > 20 mg/day) Regular consumption (more than once in a week) of vitamins or minerals supplements during past month Chronic kidney disease stage 4 or 5

## Age

From **20 years** old to **65 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant

## Sample size

Target sample size: **76**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this study, 76 subjects with previous history of hypertension and on hypertension medication will be randomized into two groups: barberry or placebo for 2 months. Stratified block randomization will be employed to assign subject to each of the two groups. Stratification subdivides patients into those with diabetes or without diabetes and in each stratum, blocks of size 4 (two intervention and two placebo) will be defined and then the patients within each block will be assigned to intervention and control groups.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Patients are blinded of the type of powder they are consuming, but the main investigator who assigns patients to intervention or placebo groups is not blinded. Powders are given to patients in undetectable non-transparent packaging.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

##### Street address

No. 46, West Arghavan Ave., Farahzadi Blvd., Qods Town

##### City

Tehran

##### Province

Tehran

##### Postal code

1981619573

#### Approval date

2019-09-02, 1398/06/11

#### Ethics committee reference number

IR.SBMU.NNFTRI.REC.1398.046

## Health conditions studied

### 1

#### Description of health condition studied

hypertension

#### ICD-10 code

I10

#### ICD-10 code description

Essential (primary) hypertension

## Primary outcomes

### 1

#### Description

Flow mediated dilation (FMD)

#### Timepoint

Baseline and the end of the study

#### Method of measurement

sonography

## Secondary outcomes

### 1

#### Description

plasma ICAM-1

#### Timepoint

Baseline and the end of the study

#### Method of measurement

ELISA

### 2

#### Description

Plasma VCAM-1  
**Timepoint**  
Baseline and the end of the study  
**Method of measurement**  
ELISA

## Intervention groups

### 1

#### Description

Intervention group: Daily consumption of 10 gram of barberry powder for 8 weeks. Barberry is purchased from the local market at one time.

#### Category

Treatment - Other

### 2

#### Description

Control group: Daily consumption of 10 gram of placebo powder (Contains maltodextrin, citric acid and edible red color) for 8 weeks

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Rajaee Cardiovascular, Medical & Research Center

##### Full name of responsible person

Dr Ali Zahedmehr

##### Street address

Niyayesh intersection, Valiasr Street, Tehran

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##### Province

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##### Postal code

1995614331

##### Phone

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##### Email

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr Morteza Abdollahi

##### Street address

No. 46, Hafezi street, Farahzadi blvd, Qods Town, Tehran

##### City

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jnasrollahzadeh@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Hadi Emamat

##### Position

Ph.D. Student in Nutrition Sciences

##### Latest degree

Master

##### Other areas of specialty/work

Nutrition

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hadiemamat@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr Javad Nasrollahzadeh

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Hadi Emamat

**Position**

PhD student

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

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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**

There is no further information.

**Study Protocol**

No - There is not 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**

No - There is not 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