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 Rajaee 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

City

Tehran

Province

Tehran

Postal code

1995614331

Phone

+98 21 23921

Email

arashzahedmehr@yahoo.com

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

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2236 0658

Email

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 31 5545 0314

Email

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

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

City
Tehran

Province
Tehran

Postal code
1981619573

Phone
+98 21 2207 7424

Email
jnasrollahzadeh@gmail.com

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

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

City
Tehran

Province
Tehran

Postal code
1981619573

Phone
+98 31 5545 0314

Email
hadiemamat@yahoo.com

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