Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effects of BlackBerry (Morus nigra L.) consumption on serum concentration of lipoproteins , APO A1 , APO B and hs – CRP and blood pressure in dyslipidemic patients

Protocol summary

Summary

object: The effects of BlackBerry (Morus nigra L.) consumption on serum concentration of lipoproteins , APO A1 , APO B and hs – CRP and blood pressure in dyslipidemic patients. This study is a randomized, single-blind,multiple center with control group in the phase 3 of clinical trial. inclusion criteria: ; informed consent; dislipidemia (cholesterol > 200 mg/dl and LDL > 100 mg/dl);BMI between 20-35;age between 18-65;no consumption of any drugs affecting lipid metabolism; no consumption antioxidant supplements of at least one month prior to study entry and during study; lack of any systematic disease,inflammation ,choronic or liver and kidney disease;no pregnancy or lactation;lack of sensivity to the blackberry. Exclusion criteria: not wanting Collaboration; changes in food pattern ; systematic or choronic disease during the study; LDL higher than 160 mg/dl and necessity to medication under specialist .72 Eligible patients randomaly divided into two groups, intervention and control groups;individuals in intervention group receive 300 gr BlackBerry daily for 8 weeks and individuals in control group are asked to continue their usual diet without eating berries. The primary expected outcomes are changes in serum level of lipoproteins,Apo A1,Apo B,hs-CRP and blood pressure compared with baseline in the intervention group and the control before and after of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205182365N7**
Registration date: **2012-06-04, 1391/03/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-06-04, 1391/03/15

Registrant information

Name
Mohammad Reza Vafa
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8670 4734
Email address
vafa.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of BlackBerry (Morus nigra L.) consumption on serum concentration of lipoproteins , APO A1 , APO B and hs – CRP and blood pressure in dyslipidemic patients

Public title

The effects of BlackBerry (Morus nigra L.) consumption on serum concentration of lipoproteins , APO A1 , APO B

and hs – CRP and blood pressure in dyslipidemic patients

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: informed consent; dislipidemia (cholesterol > 200 mg/dl and LDL > 100 mg/dl);BMI between 20-35;age between 18-65; no consumption of any drugs affecting lipid metabolism; no consumption of antioxidant supplements of at least one month prior to study entry and during study lack of any systematic disease,inflammation ,choronic or liver and kidney disease;no pregnancy or lactation;no smoking and use of alcoholic beverages;lack of sensivity to the blackberry. Exclusion criteria: not wanting Collaboration; changes in food pattern ; systematic or choronic disease during the study; LDL higher than 160 mg/dl and necessity to medication under specialist.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Sixth Floor,Central Organization of Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd

City

Tehran

Postal code

Approval date

2012-05-16, 1391/02/27

Ethics committee reference number

130/2828/90/د

Health conditions studied

1

Description of health condition studied

dislipidemia

ICD-10 code

E78.5

ICD-10 code description

Hyperlipidaemia, unspecified

Primary outcomes

1

Description

Total cholesterol

Timepoint

Before and after intervention

Method of measurement

Colorimetric

2

Description

LDL-cholesterol

Timepoint

Before and after intervention

Method of measurement

Colorimetric

3

Description

HDL-cholesterol

Timepoint

Before and after intervention

Method of measurement

Colorimetric

4

Description

TG

Timepoint

Before and after intervention

Method of measurement

Colorimetric

5

Description

APO A1

Timepoint

Before and after intervention

Method of measurement

turbidimetry

6

Description

APO B

Timepoint

Before and after intervention
Method of measurement
turbidimetry

7

Description
hs-CRP
Timepoint
Before and after intervention
Method of measurement
ELISA

8

Description
Systolic blood pressure
Timepoint
Before and after intervention
Method of measurement
Mercury barometer

9

Description
Diastolic blood pressure
Timepoint
Before and after intervention
Method of measurement
Mercury barometer

Secondary outcomes

1

Description
weight
Timepoint
Before and after intervention
Method of measurement
scale

2

Description
height
Timepoint
Before and after intervention
Method of measurement
meter

3

Description
BMI
Timepoint
Before and after intervention
Method of measurement
mathematics

4

Description
Waist circumference
Timepoint
Before and after intervention
Method of measurement
meter

5

Description
Energy intake
Timepoint
Before and after intervention
Method of measurement
recall

6

Description
Protein intake
Timepoint
Before and after intervention
Method of measurement
recall

7

Description
Carbohydrate intake
Timepoint
Before and after intervention
Method of measurement
recall

8

Description
fat intake
Timepoint
Before and after intervention
Method of measurement
recall

9

Description
cholesterol intake
Timepoint
Before and after intervention
Method of measurement
recall

10

Description
fiber intake
Timepoint
Before and after intervention
Method of measurement
recall

11

Description
Vitamin A

Timepoint
Before and after intervention
Method of measurement
recall

12

Description
Vitamin C
Timepoint
Before and after intervention
Method of measurement
recall

13

Description
Vitamin E
Timepoint
Before and after intervention
Method of measurement
recall

14

Description
sodium
Timepoint
Before and after intervention
Method of measurement
recall

15

Description
potasium
Timepoint
Before and after intervention
Method of measurement
recall

16

Description
fruit and vegetables intake
Timepoint
Before and after intervention
Method of measurement
recall

17

Description
level of physical activity
Timepoint
Before and after intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
Black berry , 300 gr , once a day for 8 weeks
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tamin ejtemaei clinic ,Razi hospital
Full name of responsible person
Dr Davood Katebi
Street address
Razi hospital-shahid babaei St-Qazvin
City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Aliakbar Fotouhi
Street address
Research section-Tehran University of Medical Sciences- Ghods st- Keshavarz Blvd- Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Reza Vafa
Position

Associate Professor

Other areas of specialty/work

Street address

Department of Nutrition-School of Public Health-Tehran University of Medical Sciences-Alvand st.-Argentine Square- Tehran

City

Tehran

Postal code

Phone

+98 21 8877 9118

Fax

Email

rezavafa@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Vafa

Position

PhD of Nutrition sciences

Other areas of specialty/work

Street address

Department of Nutrition- Health school- Tehran University of Medical Sciences-Alvand st.- Argentine Square- Tehran

City

Tehran

Postal code

Phone

+98 21 8877 9118

Fax

Email

mrvafa@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Vafa

Position

PhD of Nutrition sciences

Other areas of specialty/work

Street address

Department of Nutrition- Health school- Tehran University of Medical Sciences-Alvand st.- Argentine Square- Tehran

City

Tehran

Postal code

Phone

+98 21 8877 9118

Fax

Email

mrvafa@tums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty