

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effects of olive (*Olea europaea*) leaf extract on blood pressure and oxidative stress parameters and lipid profiles in patients with hypertension

Protocol summary

Summary

Objectives: determining the effect of olive (*Olea europaea*) leaf extract on blood pressure and oxidative stress parameters and lipid profiles in patients with hypertension. Design: parallel double-blind randomized controlled clinical trial. Inclusion criteria: subjects with systolic blood pressure (SBP) above 140 mmHg or diastolic blood pressure (DBP) above 90 mmHg. Exclusion criteria: patients who do not want to cooperate; hypertensive patients who have other complications such as: kidney disease, neuropathy and retinopathy, patients with hypo and/or hyperthyroidism are excluded from this study. Population and sample size: 60 subjects with hypertension, eligible and referred to Boo-Ali hospital affiliated to Qazvin University of Medical Sciences, Qazvin, Iran will be selected. Intervention: patients will be assigned to receive either 500 mg olive (*Olea europaea*) leaf extract (intervention group: n=30) or placebo (control group: n=30). Fasting blood samples will be taken at baseline and after 12-wk intervention to evaluate status of oxidative stress and lipid profiles. Outcomes: blood pressure, status of oxidative stress such as MDA and total antioxidant capacity and lipid profile such as total cholesterol, triglyceride, HDL and LDL will be measured at baseline and end-of-trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017043033730N1**

Registration date: **2017-05-31, 1396/03/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-31, 1396/03/10

Registrant information

Name

Seyyed Mehdi Mirhashemi

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6001

Email address

sm.mirhashemi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Qazvin University of Medical Sciences, Qazvin University of Medical Sciences,

Expected recruitment start date

2017-05-08, 1396/02/18

Expected recruitment end date

2017-06-08, 1396/03/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of olive (*Olea europaea*) leaf extract on blood pressure and oxidative stress parameters and lipid profiles in patients with hypertension

Public title

Olive (*Olea europaea*) leaf extract on blood pressure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: subjects with systolic blood pressure (SBP) above 140 mmHg or diastolic blood pressure (DBP) above 90 mmHg. Exclusion criteria: patients who do not want to cooperate; hypertensive patients who have others complications such as: kidney disease: neuropathy and retinopathy; patients with hypo and/or hyperthyroidism are excluded from this study.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Shahid Bahonar Blvd

City

Qazvin

Postal code

Approval date

2017-01-25, 1395/11/06

Ethics committee reference number

IR.QUMS.REC.1395.264

Health conditions studied

1

Description of health condition studied

Essential hypertension

ICD-10 code

I10

ICD-10 code description

Hypertensive diseases

Primary outcomes

1

Description

Blood Pressure

Timepoint

Before and after intervention

Method of measurement

based on mmHg using sphigmomanometer

2

Description

MDA

Timepoint

Before and after intervention

Method of measurement

Elisa

3

Description

Total antioxidant capacity

Timepoint

Before and after intervention

Method of measurement

spectrophotometric

4

Description

Lipid profiles

Timepoint

Before and after intervention

Method of measurement

spectrophotometric

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: olive leaf extract as 250 mg tablet, orally ,twice a day for 12 weeks.

Category

Treatment - Drugs

2

Description

The control group: Cellulose as 250 mg tablet as placebo, orally twice a day for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Boo-Ali Hospital

Full name of responsible person

Dr Seyyed Mehdi Mirhashemi

Street address

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Qazvin University of Medical Sciences

Full name of responsible person

Dr Seyyed Mehdi Mirhashemi

Street address

Vice Chancellor for research of Qazvin University of Medical Sciences- Shahid Beheshti Blvd-Qazvin

City

Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Seyyed Mehdi Mirhashemi

Position

PhD in Clinical Biochemistry

Other areas of specialty/work

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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