

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Olive (*Olea europaea*) leaf extract effect on glucose metabolism and liver function and biomarkers of inflammation in patients with high blood presurer

Protocol summary

Study aim

Determining the effect of olive (*Olea europaea*) leaf extract on glucose metabolism and liver function and biomarkers of inflammation in patients with hypertension.

Design

Random assignment was done by the use of computer-generated random numbers. Population and sample size: In the study 60 patients with high blood pressure among males and females of eligible and referred to health and clinical centers affiliated to Qazvin University of Medical Sciences, Qazvin, Iran, were selected.

Settings and conduct

In the study 60 patients with high blood pressure among males and females of eligible and referred to health and clinical centers affiliated to Qazvin University of Medical Sciences, Qazvin, Iran, were selected.

Participants/Inclusion and 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 did not want to cooperate; hypertensive patients who had others complications such as: kidney disease: neuropathy and retinopathy, patients with hypo and/or hyperthyroidism were excluded from this study.

Intervention groups

Patients were assigned to receive either extract (intervention group: n=30) or placebo (control group: n=30).

Main outcome variables

Glucose metabolism, liver function and biomarkers of inflammation in patients with high blood pressure were measured before and after of the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170430033730N5**

Registration date: **2018-09-25, 1397/07/03**

Registration timing: **retrospective**

Last update: **2018-09-25, 1397/07/03**

Update count: **0**

Registration date

2018-09-25, 1397/07/03

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

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

2017-12-05, 1396/09/14

Actual recruitment end date

2018-03-07, 1396/12/16

Trial completion date

2018-08-20, 1397/05/29

Scientific title

Olive (<i>Olea europaea</i>) leaf extract effect on glucose metabolism and liver function and biomarkers of inflammation in patients with high blood presurer		Qazvin
Public title		Province
Olive (<i>Olea europaea</i>) leaf extract effect on glucose and inflammation		Qazvin
Purpose		Postal code
Treatment		3419759811
Inclusion/Exclusion criteria		Approval date
Inclusion criteria:		2017-09-02, 1396/06/11
Systolic blood pressure (SBP) above 140 mmHg Diastolic blood pressure (DBP) above 90 mmHg.		Ethics committee reference number
Exclusion criteria:		IR.QUMS.REC.1396.240
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		Health conditions studied
From 30 years old to 70 years old		<u>1</u>
Gender		Description of health condition studied
Both		Essential hypertension
Phase		ICD-10 code
N/A		I10
Groups that have been masked		ICD-10 code description
No information		Essential (primary) hypertension
Sample size		
Target sample size: 60		
Actual sample size reached: 60		
Randomization (investigator's opinion)		
Randomized		
Randomization description		
Simple randomization, Random assignment was done by the use of computer-generated random numbers.		
Blinding (investigator's opinion)		
Double blinded		
Blinding description		
A placebo was used to blind. Researchers and Patients will be blinded by the professional analyst until final analysis.		
Placebo		
Used		
Assignment		
Parallel		
Other design features		
Secondary Ids		
empty		
Ethics committees		
<u>1</u>		
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		

Method of measurement

Spectrophotometry

3**Description**

ALKP

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

4**Description**

TP

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

5**Description**

Alb

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

6**Description**

TNF- α

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

ELISA

7**Description**

IL-6

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

ELISA

8**Description**

IL-8

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

ELISA

9**Description**

hs-CRP

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

ELISA

10**Description**

Omentin

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

ELISA

11**Description**

BUN

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

12**Description**

Creatinin

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

13**Description**

Uric Acid

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

Intervention groups**1****Description**

Intervention group: Two capsules of 275 mg of extract were taken twice daily for twelve weeks

Category

Treatment - Drugs

2**Description**

Control group: Two capsules of 250 mg of placebo were taken twice a day for 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Boo-Ali Hospital

Full name of responsible person

Dr Seyyed Mehdi Mirhashemi

Street address

Shahid Bahonar Blovard

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Qazvin

Province

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34197 - 59811

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mirhashemism@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Amir Peimani

Street address

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

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a.peymani@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Seyyed Mehdi Mirhashemi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Person responsible for scientific inquiries

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Full name of responsible person

Seyyed Mehdi Mirhashemi

Position

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Latest degree

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Other areas of specialty/work

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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

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable