Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Nov 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 wrere 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 werevmeasured 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)

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+98 28 3333 6001

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

Public title
Olive (Olea europaea) leaf extract effect on glucose and inflammation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Systolic blood pressure (SBP) above 140 mmHg 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 **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
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

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
Province
Qazvin
Postal code
3419759811
Approval date
2017-09-02, 1396/06/11
Ethics committee reference number
IR.QUMS.REC.1396.240

Health conditions studied

1

Description of health condition studied
Essential hypertension
ICD-10 code
I10
ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
FBS
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement
Spectrophotometry

2

Description
Insulin
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement
ELISA

Secondary outcomes

1

Description
AST
Timepoint
At the beginning of the study and 12 weeks after the intervention
Method of measurement
Spectrophotometry

2

Description
ALT
Timepoint
At the beginning of the study and 12 weeks after the intervention

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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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

Contact

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Full name of responsible person

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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