

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation anti-hyperlipidemia effect of *Pistacia atlantica* Desf. ssp. *Kurdica* versus placebo in diabetic patients: A triple blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the anti-hyperlipidemia effect of *Pistacia atlantica* Desf. ssp. *Kurdica* versus placebo in diabetic patients. **Design:** A triple blind randomized clinical trial. **Setting and conduct:** The eligible diabetic patients who will refer to Shahid Beheshti Hospital during the study period will be enrolled into the trial. **Inclusion criteria:** Age of 18 to 65 years; hypercholesterolemia; HbA1C between 6 to 10. **Exclusion criteria:** Renal disease; Liver disorder; gastric problem; heart failure; brain disease; sensitivity to *Pistacia Atlantica* *Kurdica*; insulin usage; myopathy. **Intervention group:** Tablet Atorvastatin 40 mg once a day for 2 months plus capsule including dried powder of *Pistacia Atlantica* *Kurdica* 2 gr once a day for 2 months. **Control group:** Tablet Atorvastatin 40 mg once a day for 2 months plus capsule including starch 2 gr once a day for 2 months. **Primary outcome:** (a) assessing serum cholesterol before and 1 and 2 months after intervention through laboratory test; (b) assessing blood sugar before and 1 and 2 months after intervention through laboratory test. **Secondary outcome:** Assessing side effects including nausea and vomiting 1 and 2 months after intervention through history taking. **Randomization:** The patients will be randomly assigned to intervention and control groups using block randomization. **Blinding:** Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201708109014N178**

Registration date: **2017-08-13, 1396/05/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-08-13, 1396/05/22

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation anti-hyperlipidemia effect of Pistacia atlantica Desf. ssp. Kurdica versus placebo in diabetic patients: A triple blind randomized clinical trial

Public title
Evaluation anti-hyperlipidemia effect of Pistacia atlantica Desf. ssp. Kurdica versus placebo in diabetic patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Age of 18 to 65 years; hypercholesterolemia; HbA1C between 6 to 10. Exclusion criteria: Renal disease; Liver disorder; gastric problem; heart failure; brain disease; sensitivity to Pistacia Atlantica Kurdica; insulin usage; myopathy.

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **58**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2017-07-08, 1396/04/17

Ethics committee reference number

IR.UMSHA.REC.1396.311

Health conditions studied

1

Description of health condition studied

Hyperlipidemia

ICD-10 code

E78.5

ICD-10 code description

Hyperlipidaemia, unspecified

Primary outcomes

1

Description

assessing serum cholesterol

Timepoint

before and 1 and 2 months after intervention

Method of measurement

through laboratory test

2

Description

assessing blood sugar

Timepoint

before and 1 and 2 months after intervention

Method of measurement

through laboratory test

Secondary outcomes

1

Description

Assessing side effects including nausea and vomiting

Timepoint

1 and 2 months after intervention

Method of measurement

through history taking

Intervention groups

1

Description

Intervention group: Tablet Atorvastatin 40 mg once a day for 2 months plus capsule including dried powder of Pistacia Atlantica Kurdica 2 gr once a day for 2 months.

Category

Treatment - Drugs

2

Description

Control group: Tablet Atorvastatin 40 mg once a day for 2 months plus capsule including starch 2 gr once a day for 2 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Faezeh Safari Majd

Street address

Shahid Beheshti Hospital, Eram Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

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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 and Technology, Hamadan
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

School of Pharmacy

Full name of responsible person

Faezeh Safari Majd

Position

Pharmacology Student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work

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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