Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Evaluation of the effect of Pistacia atlantica oleoresin on fasting blood sugar in patients with type 2 diabetes and its relationship with lipid profile and blood pressure A randomized, single-blind, placebo-controlled trial

Protocol summary

Study aim
Evaluation of the effect of Pistacia atlantica oleoresin on fasting blood sugar in patients with type 2 diabetes and its relationship with lipid profile and blood pressure

Design
Clinical trial with control group,single blind, randomized, phase 3 on 42 patients. In this study, the allocation of samples to the study groups will be stratified randomization.

Settings and conduct
This study is performed on patients referred to Deziani Diabetes Clinic with a definitive diagnosis of type 2 diabetes. In this study, 42 patients were selected and randomly divided into two groups of control and case, each group of 21 people. In the intervention group, Pistacia atlantica oleoresin capsules in a dose of 500 mg twice a day for three consecutive months, in addition to blood sugar lowering drug (metformin tablets) will be received. In the control group, they will only receive blood sugar-lowering drug (metformin tablets) for three consecutive months.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 30-64 years, whose definitive diagnosis of diabetes Patients with a history of type 2 diabetes HbA1c is more equal to 8% and less than 9%. Exclusion criteria: blood sugar more than 300 and HbA1c is more equal to 9% . indications for starting insulin Moderate to severe renal insufficiency (GFR less than 45 or albuminuria more than 300 mg) Liver failure

Intervention groups
In Intervention group: Pistacia atlantica oleoresin capsules at a dose of 500 mg twice a day for three months, in addition to the anti diabetic drug (metformin tablets). In the control group, they will only use the blood sugar-lowering drug (metformin tablets) for three months.

Main outcome variables
FBS, 2HPP BS, HbA1c

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20161031030616N2**
Registration date: **2022-03-15, 1400/12/24**
Registration timing: **prospective**

Last update: **2022-03-15, 1400/12/24**
Update count: **0**

Registration date
2022-03-15, 1400/12/24

Registrant information

Name
Fatemeh Kolangi

Name of organization / entity
Babol University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-09, 1401/01/20

Expected recruitment end date
2022-10-12, 1401/07/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Pistacia atlantica oleoresin on fasting blood sugar in patients with type 2 diabetes and its relationship with lipid profile and blood pressure A randomized, single-blind, placebo-controlled trial

Public title
Evaluation of the effect of Pistacia atlantica on fasting blood sugar in patients with type 2 diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The patient's desire to enter the study Age between 30-64 years, whose definitive diagnosis of diabetes has been made by performing two FBS tests more than 126 and the approval of the relevant specialist. Patients with a history of type 2 diabetes are diagnosed less than two years after the onset of the disease and use at least one standard oral medication (metformin tablets) for initial control of the disease. HbA1c is more equal to 8% and less than 9%.
Exclusion criteria:
blood sugar more than 300 and HbA1c is more equal to 9% . Have indications for starting insulin and other injectable therapy. Patients treated with insulin Moderate to severe renal insufficiency (GFR less than 45 or albuminuria more than 300 mg) Liver failure (diagnosis by an internal medicine specialist or gastroenterologist based on bilirubin, albumin and liver enzymes) Class 3 and 4 heart failure Diabetic retinopathy Serious medical illness Simultaneous infectious diseases including pulmonary tuberculosis, diabetic foot ulcers and ... High blood pressure (systolic above 160 or diastolic above 100 mm Hg) or need to take more than three antihypertensive drugs Women who decide to get pregnant Pregnant women and lactating women
Age
From **30 years** old to **64 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the allocation of samples to the study groups will be stratified randomization. Because variables such as the presence of a history of disease (diabetes and hypertension) and gender have been identified as confounding variables in the study results according to the studies, the researcher decided to control the samples for the above variables and balance between Establish groups. Because in this study, samples will be available in the study, the researcher will also consider the matching of the studied groups in terms of the above variables when assigning samples to groups according to the permutation block method. After the number of samples in both groups reached half of the estimated number of samples, the groups were examined to ensure that matching occurred. By first selecting one of the 6 permutations (AABB-ABAB-ABBA-BAAB-BABA-BBAA) by simple random sampling without placement according to the selected block (eg AABB) Group A and the second sample with a history of disease and gender will be assigned to group A and the third and fourth samples with a history of disease and gender will be assigned to group B. In the second stage, one of the blocks will be selected and the samples will be assigned to the groups according to their permutations, and this process will continue until the required half of the sample in each group is reached. Confusing variables will be checked. If matching has occurred, the process of assigning samples to groups will continue. If no matching is performed, the simple random randomization to groups will continue.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, blinding will be one-sided blind. In this way, patients will not be aware of being in two groups and drugs will be prepared in identical forms (in terms of color, smell, and taste) in the form of capsules for both groups. At the time of assigning the samples to the study groups, the participating samples are not aware of which group of the present study they are in, and only the assignor according to the block permutations and the type of letters (A, B) assigned to each sample, Knows which group (group A or group B) the sample is in.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Golestan University of Medical Sciences
Street address
Phalsaphy complex, Shast kola Road
City
Gorgan
Province

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4918936316

Approval date

2022-02-27, 1400/12/08

Ethics committee reference number

IR.GOUMS.REC.1400.449

Health conditions studied

1

Description of health condition studied

Diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

FBS

Timepoint

At the beginning of the study (before the intervention) and At the end of three months from the start of the intervention

Method of measurement

Calorimetric by enzymatic method

2

Description

Two-hour blood sugar

Timepoint

At the beginning of the study (before the intervention) and At the end of three months from the start of the intervention

Method of measurement

Calorimetric by enzymatic method

3

Description

HbA۱C

Timepoint

At the beginning of the study (before the intervention) and At the end of three months from the start of the intervention

Method of measurement

chromatography

Secondary outcomes

1

Description

Blood serum cholesterol level of patients

Timepoint

At the beginning of the study (before the intervention) and At the end of three months from the start of the intervention

Method of measurement

Calorimetric by enzymatic method

2

Description

Blood serum triglyceride level of patients

Timepoint

At the beginning of the study (before the intervention) and At the end of three months from the start of the intervention

Method of measurement

Calorimetric by enzymatic method

3

Description

Blood serum LDL cholesterol level of patients

Timepoint

At the beginning of the study (before the intervention) and At the end of three months from the start of the intervention

Method of measurement

Calorimetric by enzymatic method

4

Description

Blood serum HDL cholesterol level of patients

Timepoint

At the beginning of the study (before the intervention) and At the end of three months from the start of the intervention

Method of measurement

Calorimetric by enzymatic method

5

Description

systolic blood pressure

Timepoint

At the beginning of the study (before the intervention) and At the end of three months from the start of the intervention

Method of measurement

Blood pressure device

6

Description

diastolic blood pressure

Timepoint

At the beginning of the study (before the intervention) and At the end of three months from the start of the intervention

Method of measurement

Blood pressure device

Intervention groups

1

Description
In this study, 42 patients were selected and divided into two groups of control and case, each group of 21 people.In this study, the allocation of samples to the study groups will be stratified randomization. In the intervention group, they will receive Pistacia atlantica oleoresin capsules in a dose of 500 mg twice a day for three consecutive months, in addition to a hypoglycemic drug (metformin tablets).The drug will be delivered to patients monthly.Before the start of the study, fasting blood sugar tests, 2hpp BS, Hb A1C and serum lipids are measured and then patients are included in the study.Then, after 3 months, a blood test is taken again and all 3 factors of fasting blood sugar, 2hpp BS, Hb A1C and serum lipids are measured.

Category
Treatment - Drugs

2

Description
Control group: 21 patients will be in the control group. anti diabetic drug (metformin tablets) for three months.In this study, the allocation of samples to the study groups will be stratified randomization. drugs will be delivered to patients on a monthly basis.Before the start of the study, fasting blood sugar tests, 2hpp BS, Hb A1C and serum lipids are measured and then patients are included in the study.Then, after 3 months, a blood test is taken again and all 3 factors of fasting blood sugar, 2hpp BS, Hb A1C and serum lipids are measured.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Gorgan Deziani Diabetes Clinic

Full name of responsible person
Fatemeh Kolangi

Street address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gorgan University of Medical Sciences

Full name of responsible person
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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
Gorgan 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
Gorgan University of Medical Sciences

Full name of responsible person
Fatemeh Kolangi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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