Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of French Maritime Pine Bark Extract (Oligopin®) on FBS, LDL ,HDL and systolic blood pressure in women with type II diabetic

Protocol summary

Study aim
French Maritime Pine Bark Extract antidiabetic effects and cardiovascular risk factors improvement review. Encouraging diabetic patients to use French Maritime Pine Bark Extract as alternative for chemically decreasing glucose agents, and metabolic syndrome risk factors improvement after supplement using

Design
The present study was designed in a double blinded randomized clinical trial in two groups of placebo and placebo with blood sampling in two rounds (before and after supplement take).

Settings and conduct
This research will be conducted in the clinic of diabetes of Imam Khomeini Hospital in Tehran.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women with type 2 diabetes from at least 3 years ago till now and mild to moderate systolic blood pressure (120-159 mm Hg) Exclusion criteria: Insulin usage, pregnancy and lactation, daily use of any supplement except multivitamin, major diseases such as cancer, asthma , heart failure and other cardiovascular problems.

Intervention groups
The only intervention in this project is French Maritime Pine Bark Extract (Oligopin) use and the complementary placebo in two randomized groups of 15 people each.

Main outcome variables
Fasting blood glucose, Low density lipoprotein, High density lipoprotein &Systolic blood pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180718040512N1**
Registration date: **2018-08-04, 1397/05/13**
Registration timing: **registered_while_recruiting**
Last update: **2019-03-12, 1397/12/21**
Update count: **1**

Registration date
2018-08-04, 1397/05/13

Registrant information

Name
Rasool Orouji

Name of organization / entity
Payame Noor University

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Iran (Islamic Republic of)

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orouji@health.gov.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-29, 1397/05/07

Expected recruitment end date
2018-09-23, 1397/07/01

Actual recruitment start date
2018-07-29, 1397/05/07

Actual recruitment end date
2018-09-16, 1397/06/25

Trial completion date
2018-09-16, 1397/06/25

Scientific title
The effect of French Maritime Pine Bark Extract (Oligopin®) on FBS, LDL ,HDL and systolic blood pressure in women with type II diabetic

Public title
Evaluation of the effect of French Maritime Pine Bark Extract on selected blood type indices in type 2 diabetic women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Female At least three years of type 2 diabetes history Having mild to moderate systolic blood pressure (120-159 mm Hg)

Exclusion criteria:

Male Having type 1 diabetes Insulin usage Daily usage of any supplement multivitamin Suffering from any major diseases such as cancer, asthma , heart failure and other cardiovascular Disorders Pregnancy and lactation

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Following notification and inviting the patients for further cooperation in the research project, the goals and research methodology were provided to the them and filled the informed consent& questionnaires.A sample of 30 people divided randomly into two homogenous groups of 15 people each. One group uses two 50 mg capsules of oligopin supplement per day for 6 weeks and in the same time the other group will use proprietary placebo

Blinding (investigator's opinion)

Double blinded

Blinding description

Thirty people are randomly will be assign to one of two homogeneous supplement and placebo groups of 15 people each.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Payam Noor University ethics committee

Street address

Payame Noor University Headquarter, Nakhl Alley ,the beginning of Shahrak Naft township, Artesh Blvd, Mini City, Tehran.

City

Tehran

Province

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Postal code

193954697

Approval date

2018-06-09, 1397/03/19

Ethics committee reference number

IR.PNU.REC.1397.009

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Fasting blood glucose, Low density lipoprotein, High density lipoprotein &Systolic blood pressure

Timepoint

Blood sampling is two times before and after supplement take (beginning of the study and six weeks after supplement take)

Method of measurement

The variable of blood pressure is taken by a digital barometric device in the clinic, and other blood biochemical variables will be performed by the relevant specialist in the clinic laboratory.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: French Marine Pine Extract (Oligopin) users

Category

Prevention

2

Description

Control group: Placebo users

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Diabetic Clinic of Imam Khomeini Hospital

Full name of responsible person
Dr. Manouchehr Khan Nakhjavani

Street address
Imam Khomeini Hospital, Dr Gharib Ave, end of Keshavarz Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Payam Noor University

Full name of responsible person
Dr. Reza Haji Hosseini

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No. 3, Hakimeh, Panzdah Metri Shirazi Ave, Sazeman Abb St, Hakimieh.

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Web page address
http://teh-shargh.pnu.ac.ir/Portal/Home/

Grant name

Grant code / Reference number

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

Title of funding source
Payam Noor University

Proportion provided by this source
1

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Payam Noor University

Full name of responsible person
Rasool Orouji

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Biochemistry

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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
Due to the confidentiality of the research participants, information, I do not intend to publish the research participants, data.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available