Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of pine bark extract supplementation on metabolic status , serum levels of ICAM-1 and VCAM-1 and anthropometric indeces in type 2 diabetic patients with microalbuminuria

Protocol summary

Study aim

The effects of pine bark extract supplementation on metabolic status and serum levels of ICAM1, VCAM1 and anthropometric indices in type 2 diabetes mellitus patients with microalbuminuria

Design

Randomized, double-blind, placebo-controlled study population: Individuals with type 2 diabetes with microalbuminuria were randomly divided into 2 groups, including pine bark extract recipients and placebo recipients, for 8 weeks. Sample size: 46 people (2 groups of 23 persons). Study Intervention: pine bark extract supplement

Settings and conduct

For each person, the general characteristics questionnaire, anthropometric evaluations, nutrition inventory and the International Assessment of Physical Activity IPAQ will be completed. To measure all biochemical parameters, 10cc of venous blood is collected fasting (at the beginning and end of the study) and their serum will be separated and kept at -70° until testing. To obtain the ratio of albumin to creatinine, a randomized urine sample will be taken and kept at -20°.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women 30-50, and men 30-65 years old, Microalbuminuria diagnosis based on ACR criteria in randomized urine specimen; Exclusion criteria: history of heart failure; Infectious diseases of the urine and prostate; Acute febrile illness; uncontrolled blood pressure and blood glucose; Glomerulonephritis; Polycystic kidney disease; nephropathy; Insulin therapy; smoking; Pregnancy-lactation

Intervention groups

Group 1 receiving pine bark extract (2 capsules of 50 mg) Group 2 receiving placebo (2 capsules of 50 mg containing starch)

Main outcome variables

Effect of pine bark extract supplementation on metabolic status, serum level of ICAM1, VCAM1 and anthropometric indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100408003664N21**
Registration date: **2018-04-26, 1397/02/06**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-26, 1397/02/06**
Update count: **0**

Registration date

2018-04-26, 1397/02/06

Registrant information

Name

Maryam Rafraf

Name of organization / entity

Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pine bark extract supplementation on metabolic status , serum levels of ICAM-1 and VCAM-1 and anthropometric indeces in type 2 diabetic patients with microalbuminuria

Public title

Effect of pine bark extract on the treatment of patients with type 2 diabetes with microalbuminuria

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Volunteered to participate in the study with type 2 diabetes People (men and women) who have been diagnosed with diabetes for at least one year. Age:Women 30-50 years old Men: 30-65 years old Microalbuminuria diagnosis based on ACR criteria in randomized urine specimen

Exclusion criteria:

history of congestive heart failure,Infectious diseases of the urine, prostate,Acute febrile illnessUncontrolled blood pressureGlomerulonephritisPolycystic kidney disease,Acute hyperglycemia,The field of hereditary nephropathy Insulin therapy smoking Extreme sports activity (24 hours before sample collection) Pregnancy-lactation Use of any type of multi-vitamin supplement and so on during the study

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were selected using available methods and randomly assigned random blocks of 4 volumes to the study groups.A random sequence is generated using the STATA14 software.During the random assignment, individuals in the groups will be classified according to age, sex and BMI variables

Blinding (investigator's opinion)

Double blinded

Blinding description

A placebo and supplement will be packed in the same number in similar envelopes. The method of blindness will be that the supplements and placebo will be delivered to the participants by someone other than the researcher, and the researcher will remain unaware until the end of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Research Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz - GolgaSht - Attar Neyshabour Ave - Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5138663134

Approval date

2018-02-24, 1396/12/05

Ethics committee reference number

IR.TBZMED.REC.1396.1079

Health conditions studied

1

Description of health condition studied

Type 2 diabetes with microalbuminuria

ICD-10 code

E11.2

ICD-10 code description

Type 2 diabetes mellitus with renal complications

Primary outcomes

1

Description

Fasting blood sugar

Timepoint

Before of Intervention and 8 Weeks After Intervention

Method of measurement

Blood Sampling and Analysing With Spectrophotometer

2

Description

Level of Serum Insulin

Timepoint

Before of Intervention and 8 Weeks After Intervention

Method of measurement
Blood Sampling and Analysing With ELISA

3

Description
Homeostatic Model Assessment of Insulin Resistance(HOMA-IR)
Timepoint
Before of Intervention and 8 Weeks After Intervention
Method of measurement
Calculated According to The Formula

4

Description
HbA1C
Timepoint
Before of Intervention and 8 Weeks After Intervention
Method of measurement
Blood Sampling and Analysing With HPLC

5

Description
Total Cholestrol
Timepoint
Before of Intervention and 8 Weeks After Intervention
Method of measurement
Blood Sampling and Analysing With Spectrophotometer

6

Description
HDL-C
Timepoint
Before of Intervention and 8 Weeks After Intervention
Method of measurement
Blood Sampling and Analysing With Spectrophotometer

7

Description
LDL-C
Timepoint
Before of Intervention and 8 Weeks After Intervention
Method of measurement
Calculated According to The Friedwald Formula

8

Description
TG
Timepoint
Before of Intervention and 8 Weeks After Intervention
Method of measurement
Blood Sampling and Analysing With Spectrophotomete

9

Description
ICAM-1(Intra cellular adhesion molecule1)
Timepoint
Before of Intervention and 8 Weeks After Intervention
Method of measurement
Blood Sampling and Analysing With ELISA

10

Description
VCAM-1(vascular cell adhesion molecule 1)
Timepoint
Before of Intervention and 8 Weeks After Intervention
Method of measurement
Blood Sampling and Analysing With ELISA

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Pine bark extract (Oligopin) will be taken as two capsules of 50 mg with a meal (breakfast and lunch) for 8 weeks, the product of Aramis Faramad Company
Category
Treatment - Drugs

2

Description
Control group: 50 mg capsule containing starch 2 pcs. Per day with meals (breakfast and lunch) for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Elham Navval Esfahlan
Street address
East Azarbaijan - Tabriz - Golghaste St, next to Tabriz University - Imam Reza Hospital
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elham.naval@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
alireza ostad rahimi

Street address
Tabriz University of Medical Science,Nutrition Faculty,Attar Neyshabori,Golgasht Street

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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Elham navval esfahlan

Position
Master's Degree in Nutrition Sciences

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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Person responsible for updating data

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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