Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Iranian propolis supplementation on proteinuria, 24 hour urine, serum creatinine, prooxidant-antioxidant Balance, Glycemic indices, quality of life and blood pressure in patients with chronic kidney disease: a randomized, double-blind, placebo-controlled trial

Protocol summary

Study aim

Effects of Iranian propolis supplementation on proteinuria, 24 hour urine, serum creatinine, prooxidant-antioxidant Balance, Glycemic indices, quality of life and blood pressure in patients with chronic kidney disease

Design

a randomized, double-blind, placebo-controlled trial

Settings and conduct

This study is done at Tabriz University of Medical Sciences. After simple sampling and stratified randomized allocation and being double blind, the intervention is performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • The tendency to participate in the study • Having stage 2 or 3 CKD according to eGFR of 30-89 ml/min per 1.73 m2 • Aged 20-80 years old Exclusion criteria: • BMI less than 18.5 or more than 35 kg/ m2 • Kidney transplant recipients • Pregnancy or breastfeeding • Having any kind of allergy or asthma • Receiving immune system suppressors • Taking herbals in the last 3 months • Smoking, Being addicted, consuming alcohol or opioids • Professional athletes • Having chronic inflammatory disease

Intervention groups

Subjects in the intervention group received daily 250 mg Propolis extract containing 72 mg total amount of phenolic compounds (2 capsules containing 125 mg Propolis extract and whom in the control group received 1000 mg of placebo daily (Because the final weight of each propolis capsule is 500 mg) for 90 days.

Main outcome variables

Effects of Iranian propolis supplementation on proteinuria, 24 hour urine, serum creatinine, prooxidant-antioxidant Balance, Glycemic indices, quality of life and blood pressure in patients with chronic kidney disease

General information

Reason for update

1) Elimination of proteinuria (Protein excretion greater than 300 mg/day) with microalbuminuria (Urinary albumin to creatinine ratio greater than 30 mg/g) or macroalbuminuria (Urinary albumin to creatinine ratio greater than 300 mg / g) from Inclusion criteria. 2) Changing the age range of 18-64 to 20-80 years in the inclusion criteria; According to the age group of CKD patients observed in the sampling process. Along with the addition of matching the intervention and placebo groups in terms of age as 20-60 and 60-80 years. 3) Elimination of insulin intake from the exclusion criteria according to the opinion of Dr. Mohammad Reza Ardalan, a nephrology consultant (as stated in the proposal, the two groups of intervention and placebo will be matched in terms of diabetes). 4) Changing the expected recruitment end date to 2021/10/22 due to current Covid-19 pandemic conditions *All the mentioned changes have been approved by the ethics committee of Tabriz University of Medical Sciences and have been registered.

Acronym

IRCT registration information

IRCT registration number: **IRCT20191218045798N1**
Registration date: **2020-06-07, 1399/03/18**
Registration timing: **prospective**

Last update: **2021-08-30, 1400/06/08**
Update count: **1**

Registration date

2020-06-07, 1399/03/18

Registrant information

Name

Paniz Anvari fard

Name of organization / entity

Country
Iran (Islamic Republic of)
Phone
+98 41 3381 3665
Email address
panizanvari@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-07-22, 1399/05/01
Expected recruitment end date
2021-10-22, 1400/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of Iranian propolis supplementation on proteinuria, 24 hour urine, serum creatinine, prooxidant-antioxidant Balance, Glycemic indices, quality of life and blood pressure in patients with chronic kidney disease: a randomized, double-blind, placebo-controlled trial

Public title
Effects of Iranian propolis supplementation on chronic kidney disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The tendency to participate in the study Having stage 2 or 3 CKD according to eGFR of 30-89 ml/min per 1.73 m2 Aged 20-80 years old
Exclusion criteria:
BMI less than 18.5 or more than 35 kg/ m2 Kidney transplant recipients Pregnancy or breastfeeding Having any kind of allergy or asthma Receiving steroids or other immune system suppressors Taking herbals in the last 3 months Smoking, Being addicted, consuming alcohol or opioids Professional athletes Having chronic inflammatory disease (rheumatoid arthritis, IBD), severe depression, schizophrenia, severe liver failure, liver cirrhosis, cancers, severe infection
Age
From **20 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
This study is a randomized, double-blinded, placebo-controlled clinical trial. Among patients with chronic kidney disease (CKD) referred to specialized clinics of Tabriz, 44 patients who met the inclusion criteria were selected by simple sampling. These patients were randomly allocated to intervention or control groups (each with 22 patients), and matching between groups was done based on age and whether or not they had diabetes.
Blinding (investigator's opinion)
Double blinded
Blinding description
Randomization is performed by a person who has no involvement in the process of caring for or following up on patients. After random allocation, by using double-blind method patients are unaware of the type of intervention performed for each group. For blindness, at the beginning of the study, a set of cans containing propolis or placebo capsules are encoded by someone other than the researcher as A or B. Patients are followed up for three months, after which the blindness is broken.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of tabriz university of medical sciences
Street address
No.44, 6 meter bahar., mokhaberat street., 35 meter sina.,elgoli., Tabriz town
City
Tabriz
Province
East Azarbaijan
Postal code
5167717998
Approval date
2020-05-18, 1399/02/29
Ethics committee reference number
IR.TBZMED.REC.1399.177

Health conditions studied

1

Description of health condition studied

chronic kidney disease (CKD)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

improvement in kidney function (proteinuria, 24 hour urine, serum creatinine)

Timepoint

at the beginning and end of the study

Method of measurement

24-hour urine collection to measure 24-hour urine volume and proteinuria, Jaffe's method for measuring serum creatinine

Secondary outcomes

1

Description

prooxidant-antioxidant Balance

Timepoint

at the beginning and end of the study

Method of measurement

prooxidant-antioxidant Balance method

2

Description

Glycemic indices (FBS, HbA1c, insulin) and HOMA-IR index

Timepoint

at the beginning and end of the study

Method of measurement

biochemical assessment

3

Description

quality of life

Timepoint

at the beginning and end of the study

Method of measurement

questionnaire

4

Description

blood pressure

Timepoint

at the beginning and end of the study

Method of measurement

Mercury sphygmomanometer

Intervention groups

1

Description

Intervention group: Subjects in the intervention group received daily 250 mg Propolis extract containing 72 mg total amount of phenolic compounds (2 capsules containing 125 mg Propolis extract, 1 capsule before breakfast and 1 capsule before dinner) for 90 days. Propolis capsules are produced by Asal Shahdineh Golha Company in Isfahan and propolis extract is alcoholic.

Category

Treatment - Drugs

2

Description

Control group: whom in the control group received 1000 mg of placebo daily (Because the final weight of each propolis capsule is 500 mg) for 90 days. Placebo capsules are produced by Asal Shahdineh Golha Company in Isfahan

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized clinics of Tabriz University of Medical Sciences

Full name of responsible person

MohammadReza Ardalan

Street address

No.44, 6 meter bahar., mokhaberat street., 35 meter sina.,elgoli., Tabriz town

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Tabriz

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East Azarbaijan

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5167717998

Phone

+98 41 3381 3665

Email

panizanvari@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

deputy of Research and Technology, Tabriz University of Medical Sciences

Street address

deputy of Research and Technology, Tabriz University of Medical Sciences, Azadi street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code
5166616471
Phone
+98 41 3335 7310
Email
research-vice@tbzmed.ac.ir

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
Paniz Anvari fard
Position
master of science student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
No.44, 6 meter bahar., mokhaberat street., 35 meter sina.,elgoli., Tabriz town
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Person responsible for scientific inquiries

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Full name of responsible person
Paniz Anvari fard
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Latest degree
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Person responsible for updating data

Contact

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Paniz Anvari fard
Position
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Latest degree
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Other areas of specialty/work
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panizanvari@yahoo.com

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
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