Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of sweet almond capsule on function of kidney and quality of life in patients with chronic renal failure

Protocol summary

Study aim
Evaluation of the effect of sweet almond capsule on function of kidney and quality of life in patients with chronic renal failure

Design
Patients with chronic kidney disease, stages 2 and 3, who visited Shahrvand Kidney subspecialty clinic and Baghban clinic of Sari Sample size: 60 people Clinical trial with control group, double-blind, randomized, phase 2 on 60 patients Randomization: Random Number Table

Settings and conduct
Location: Shahrvand Kidney subspecialty clinic and Baghban clinic of Sari For blinding, the patient and attending physician responsible for evaluating patients and also the researcher will be unaware of the type of treatment for each group (drug or placebo). For this purpose, after randomization and division of patients into two groups, the drug and placebo are separated by code A or B, and then they are labled by the statistical consultant. In this way, the patient, the attending physician, and the researcher will not be aware of the type of treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with chronic kidney disease stage 2 and 3, Age range 18 to 75 years Exclusion criteria: clinically unstable, malignancy, Heart Failure, previous diagnosis of primary hyperoxaluria, History of calcium oxalate kidney stone, Known allergy to almond, Liver failure, Pregnancy, Inability to communicate, Polycystic kidney disease, acute infectious disease

Intervention groups
Intervention group will receive capsules, containing 350 mg of almond, twice a day. Control group will receive placebo capsules exactly according to the original medication, twice a day. Both groups are treated for 8 weeks.

Main outcome variables
Glomerular filtration rate Serum creatinine Blood Urea Nitrogen 24-hour urine protein Serum Albumin Serum uric acid Serum potassium Blood pressure Hemoglobin Serum C-Reactive Protein (CRP) Lipid profile Fasting blood sugar Quality of Life

General information

Reason for update
Changing age of patients Completion of sampling

Acronym

IRCT registration information
IRCT registration number: **IRCT20200516047465N1**
Registration date: **2020-08-09, 1399/05/19**
Registration timing: **prospective**

Last update: **2023-07-18, 1402/04/27**
Update count: **1**

Registration date
2020-08-09, 1399/05/19

Registrant information

Name
Sedighe Meghdadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3325 5545

Email address
s.meghdadi@mazums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-05, 1399/05/15

Expected recruitment end date
2021-01-04, 1399/10/15

Actual recruitment start date
2021-01-20, 1399/11/01

Actual recruitment end date
2021-12-06, 1400/09/15
Trial completion date
2021-12-06, 1400/09/15

Scientific title
Evaluation of the effect of sweet almond capsule on function of kidney and quality of life in patients with chronic renal failure

Public title
The effect of sweet almond on chronic renal failure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with chronic kidney disease stage 2 and 3 Age range 18 to 75 years
Exclusion criteria:
Clinically unstable Malignancy Heart Failure Previous diagnosis of primary hyperoxaluria History of calcium oxalate kidney stone Known allergy to almond Liver failure Pregnancy Inability to communicate Polycystic kidney disease Acute infectious disease
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Actual sample size reached: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomization, a quadruple block randomization method is used. In this method, all permutations obtained from 2 groups are calculated as follows: 1) AABB 2) ABAB 3) ABBA 4) BABA 5) BAAB 6) BBAA Among them, using random number table, we will select samples in the following order. The selected permutation: 3, 1, 4, 5, 2, 6, 3, 1, 2, 5, 6, 4, 1, 6, 3 A is the intervention group and B is the control group. The advantage of this method is that the groups are equal.
Blinding (investigator's opinion)
Double blinded
Blinding description
For blinding, the patient and attending physician responsible for evaluating patients and also the researcher will be unaware of the type of treatment for each group (drug or placebo). For this purpose, after randomization and division of patients into two groups, the drug and placebo are separated by code A or B, and then they are labled by the statistical consultant. In this way, the patient, the attending physician, and the researcher will not be aware of the type of treatment. Drug and placebo are similar in appearance, color and smell.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
Faculty of Iranian Medicine, next to Baghban Special Clinic, Khazar Boulevard
City
Sari
Province
Mazandaran
Postal code
48168-95475
Approval date
2020-04-27, 1399/02/08
Ethics committee reference number
IR.MAZUMS.REC.1399.128

Health conditions studied

1

Description of health condition studied
Chronic kidney disease, stage 2
ICD-10 code
N18.2
ICD-10 code description
Chronic kidney disease, stage 2

2

Description of health condition studied
Chronic kidney disease, stage 3
ICD-10 code
N18.3
ICD-10 code description
Chronic kidney disease, stage 3

Primary outcomes

1

Description
Glomerular filtration rate
Timepoint

Before and after the intervention

Method of measurement

Modification of Diet in Renal Disease (MDRD) formula

Secondary outcomes

1

Description

Serum creatinine

Timepoint

before and after the intervention

Method of measurement

Laboratory blood test

2

Description

Blood Urea Nitrogen

Timepoint

before and after the intervention

Method of measurement

Laboratory blood test

3

Description

24-hour urine protein

Timepoint

before and after the intervention

Method of measurement

24-hour urine evaluation

4

Description

Serum Albumin

Timepoint

before and after the intervention

Method of measurement

Laboratory blood test

5

Description

Serum uric acid

Timepoint

before and after the intervention

Method of measurement

Laboratory blood test

6

Description

Serum potassium

Timepoint

before and after the intervention

Method of measurement

Laboratory blood test

7

Description

Blood pressure

Timepoint

before and after the intervention

Method of measurement

Sphygmomanometer

8

Description

Hemoglobin

Timepoint

before and after the intervention

Method of measurement

Laboratory blood test

9

Description

Serum C-Reactive Protein (CRP)

Timepoint

before and after the intervention

Method of measurement

Laboratory blood test

10

Description

Lipid profile

Timepoint

before and after the intervention

Method of measurement

Laboratory blood test

11

Description

Fasting blood sugar

Timepoint

before and after the intervention

Method of measurement

Laboratory blood test

12

Description

Quality of Life

Timepoint

before and after the intervention

Method of measurement

The Short Form (36) Health Survey (SF-36)

Intervention groups

1

Description

The drug is made in faculty of pharmacy, Shahid Beheshti University of Medical Sciences. Intervention group will receive capsules, containing 350 mg of almond, twice a day; 30minutes before breakfast and 30 minutes before dinner. Both groups are treated for 8 weeks.

Category

Treatment - Drugs

2

Description
The placebo is made in faculty of pharmacy, Shahid Beheshti University of Medical Sciences. Control group will receive placebo capsules exactly according to the original medication, twice a day; 30minutes before breakfast and 30 minutes before dinner. Both groups are treated for 8 weeks.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahrvand Kidney Subspecialty Clinic

Full name of responsible person
Sedighe Meghdadi

Street address
Keshavarz 44, Keshavarz Blvd

City
Sari

Province
Mazandaran

Postal code
4815733971

Phone
+98 11 3329 1784

Fax
+98 11 3341 2951

Email
sedighe.meghdadi@yahoo.com

Web page address
https://shahrvand.mazums.ac.ir/

2

Recruitment center

Name of recruitment center
Baghban Special Clinic

Full name of responsible person
Sedighe Meghdadi

Street address
Khazar Boulevard

City
sari

Province
Mazandaran

Postal code
4816895475

Phone
+98 11 3337 4545

Email
sedighe.meghdadi@yahoo.com

Web page address
https://tooba.mazums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Sedighe Meghdadi

Street address
University of the Payambar-e-Azam-17 km of Farahabad Road - Farahabad Square

City
Sari

Province
Mazandaran

Postal code
4847191971

Phone
+98 11 3354 3081

Email
sedighe.meghdadi@yahoo.com

Web page address
https://www.mazums.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Sedighe Meghdadi

Position
Assistant

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

Street address
Faculty of Iranian Medicine, next to Baghban Special Clinic, Khazar Boulevard

City
Sari

Province

Mazandaran

Postal code
4816895475

Phone
+98 11 3325 5545

Email
sedighe.meghdadi@yahoo.com

Web page address
https://rc-sonnati.mazums.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Mohammad Yousofpour

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

Street address
Faculty of Iranian Medicine, next to Baghban Clinic, Khazar Boulevard

City
Sari

Province
Mazandaran

Postal code
4816895475

Phone
+98 11 3324 3117

Email
m.yousofpoor@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Sedighe Meghdadi

Position
Assistant

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

Street address
Faculty of Iranian Medicine, next to Baghban Special Clinic, Khazar Boulevard

City
Sari

Province
Mazandaran

Postal code
4816895475

Phone
+98 11 3325 5545

Email
sedighe.meghdadi@yahoo.com

Web page address
https://rc-sonnati.mazums.ac.ir/

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Laboratory information

When the data will become available and for how long
Four months after printing the results

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Researchers working in academic and scientific institutions

From where data/document is obtainable
s.meghdadi@mazums.ac.ir

What processes are involved for a request to access data/document
Email to the researcher

Comments