

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 labeled 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 labeled 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

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 Yousofpoor
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