Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

The effect of garlic supplementation on risk factors for cardiovascular disease and renal function in patients with diabetic nephropathy

Protocol summary

Study aim
Determining the effect of garlic supplementation on risk factors for cardiovascular disease and renal function in patients with diabetic nephropathy

Design
randomized clinical trial, double-blind, randomized control group of 60 patient. Randomization is done using a valid website and a 4-block method.

Settings and conduct
This clinical trial study will be performed in the office of a nephrologist. Researchers, participants will be unaware of the allocation of treatments.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diabetic nephropathy confirmed by a specialist, clinically in stage 3 (eGFR equal to 30 to 59) or stage 4 (eGFR equal to 15 to 29) chronic kidney disease not performing hemodialysis or peritoneal dialysis, lack presence of liver, gastrointestinal, stroke and ischemic heart disease (3 months after myocardial infarction and ischemia), pulmonary disease (asthma and COPD), cancer, hypothyroidism and hyperthyroidism, gastric ulcer, infectious Especially hepatitis, allergy to garlic No pregnancy and lactation, not consuming anticoagulants such as heparin, warfarin, apixaban, yuaroxaban, penicillamine and 3 months after taking antibiotics No history of taking garlic supplements and no special diet in the last 3 months, no smoking, being in the age range of 25 to 75 years

Intervention groups
Intervention group containing: 2 Garlic tablets (each tablet contains 400 mg of garlic powder) twice a day after lunch and dinner, control group 2 placebo tablets each containing 400 mg of corn starch twice a day after lunch and dinner

Main outcome variables
Anthropometric indices, glycemic indices, lipid indices, systolic and diastolic blood pressure

General information

Reason for update
Changing the dose of the drug, placebo and the name of the company producing the drug and placebo used in the intervention group

Acronym
ندارد

IRCT registration information
IRCT registration number: **IRCT20171107037302N3**
Registration date: **2021-11-27, 1400/09/06**
Registration timing: **prospective**

Last update: **2022-01-11, 1400/10/21**
Update count: **1**

Registration date
2021-11-27, 1400/09/06

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 3434 3834
Email address
s.sarafbank@nutr.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-09-23, 1401/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of garlic supplementation on risk factors for cardiovascular disease and renal function in patients with diabetic nephropathy

Public title
Garlic supplementation in patients with diabetic nephropathy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of diabetic nephropathy confirmed by a specialist - - being in the age range of 25 to 75 years clinically in stage 3 (eGFR equivalent to 30 to 59) or stage 4 (eGFR equivalent to 15 to 29) chronic kidney disease age 25-75 years old

Exclusion criteria:
not performing hemodialysis or peritoneal dialysis presence of liver, gastrointestinal, stroke and ischemic heart disease (3 months after stroke and ischemic heart disease), pulmonary disease (asthma and COPD), cancer, hypothyroidism and hyperthyroidism, gastric ulcer, infectious especially hepatitis, garlic allergy No pregnancy and lactation not consuming drugs of anticoagulants such as heparin, warfarin, apixaban, uvaroxaban, penicillamine and 3 months after taking antibiotics No history of taking garlic supplements and no special diet in the last 3 months Not smoking

Age
From **25 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done individually. Entry of each patient into the intervention or control group is done randomly with the help of 4 blocking. This is done using a valid random number generation website. (Random number generation website:https://www.sealedenvelope.com/simple-randomiser/v1/lists)

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, patients are unaware of received intervention. Also, before beginning of intervention, garlic and placebo supplements, which are completely similar to each other, will be coded in A and B by a third person other than main researcher to keep the blinding of the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Vice Chancellor in Research Affairs-medical university of Isfahan

Street address
School of Nutrition and Food Sciences, Isfahan University of Medical Sciences, Hezar-jerib Avenue

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2021-11-15, 1400/08/24

Ethics committee reference number
IR.MUI.RESEARCH.REC.1400.342

Health conditions studied

1

Description of health condition studied
Diabetic nephropathy

ICD-10 code
E11.2

ICD-10 code description
Type 2 diabetes mellitus with kidney complications

Primary outcomes

1

Description
weight

Timepoint
Beginning of study - week 8

Method of measurement
Digital scales

2

Description
Waist circumference

Timepoint
Beginning of study - week 8

Method of measurement
strip meter

3

Description
Body mass index
Timepoint
Beginning of study - week 8
Method of measurement
formula

4

Description
Mild arm circumference
Timepoint
Beginning of study - week 8
Method of measurement
stripe meter

5

Description
Fasting blood sugar
Timepoint
Beginning of study - week 8
Method of measurement
biochemical assesment

6

Description
triglycerides
Timepoint
Beginning of study - week 8
Method of measurement
biochemical assessment

7

Description
low density lipoprotein- cholesrtol
Timepoint
Beginning of study - week 8
Method of measurement
formula

8

Description
high density lipoprotein-cholestrol
Timepoint
Beginning of study - week 8
Method of measurement
biochemical assessment

9

Description
Total cholestrol
Timepoint
Beginning of study - week 8
Method of measurement
biochemical assessment

10

Description
Fasting insulin
Timepoint
Beginning of study - week 8
Method of measurement
biochemical assessment

Secondary outcomes

1

Description
Estimated glomerular filtration rate
Timepoint
Beginning of the study - week 8
Method of measurement
Formula

2

Description
Blood urea nitrogen
Timepoint
Beginning of the study - week 8
Method of measurement
Biochemical assessment

3

Description
creatinine
Timepoint
Beginning of the study - week 8
Method of measurement
Biochemical assessment

Intervention groups

1

Description
Intervention group: Intervention group will receive 2 Garcin tablets made by Goldaru Isfahan Pharmaceutical Company each tablet containing 300 mg of garlic powder 1800-1200 micrograms of allicin and is equivalent to approximately 2 grams of fresh garlic twice a day after lunch and dinner for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: The Control group will received 2 placebo tablets made by Goldaru Isfahan Pharmaceutical Company each tablet containing 300 mg of cornstarch twice a day after lunch and dinner for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Nephrologist office Dr. Moinzadeh

Full name of responsible person
Shohreh Nikkhah

Street address
Unit 205, 2nd Floor, Farzin Building, Seyed Alikhan St., Ferdowsi St.

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saraf2shr@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Behruz Ataei

Street address
Hezar-jerib Ave

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Province
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8174673461

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ethics@behdasht.gov.ir

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Sahar Saraf-Bank

Position
Assistant Professeor

Latest degree
Ph.D.

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