

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of garlic supplementation on markers of inflammation and oxidative stress in patients with diabetic nephropathy

Protocol summary

Study aim

Determining The effect of garlic supplementation on markers of inflammation and oxidative stress 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

Oxidative stress indices and inflammatory indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130903014551N11**

Registration date: **2021-12-14, 1400/09/23**

Registration timing: **prospective**

Last update: **2022-01-09, 1400/10/19**

Update count: **1**

Registration date

2021-12-14, 1400/09/23

Registrant information

Name

Mohammad Hossein Rouhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3183

Email address

s_m_rouhani2003@yahoo.com

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 markers of inflammation and oxidative stress 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 age 25-75 years old 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

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

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-11-29, 1400/09/08

Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.375

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

Total antioxidant capacity (TAC)

Timepoint

Beginning of study - week 8

Method of measurement

Biochemical assessment

2

Description

Super oxide dismutase

Timepoint

Beginning of study - week 8

Method of measurement

Biochemical assessment

3

Description

Malon di aldehyde

Timepoint

Beginning of the study - week 8

Method of measurement

Biochemical assessment

4

Description

(CRP) C-reactive protein

Timepoint

Beginning of the study - week 8

Method of measurement

Biochemical assessment

Secondary outcomes

empty

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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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Behruz Ataei

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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

Dr. Seyed Mohammad Hossein Rouhani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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