

# 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.

**City**

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**Province**

Isfahan

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81746-73461

**Phone**

+98 31 3223 3886

**Email**

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

**City**

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**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 56 1881 4521

**Email**

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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Hezar Jarib St., Isfahan University of Medical Sciences, Faculty of Nutrition and Food Sciences

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Other areas of specialty/work**

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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