

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Evaluation effect of garlic supplementation pill on dialysis adequacy , serum albumin, PTH, calcium, phosphorus, CRP levels and blood lipid profile in patients undergoing chronic hemodialysis in Khorshid and amin hospital (Esfahan)2020-2021

#### Protocol summary

##### Study aim

Evaluation effect of garlic supplementation tablet on dialysis adequacy and serum albumin, PTH, calcium, phosphorus and CRP levels and blood lipid profile in patients undergoing chronic hemodialysis

##### Design

Randomized controlled clinical trial with parallel groups, triple-blind, of 88 patients. Random allocation software is used for randomization.

##### Settings and conduct

This study was performed in chronic kidney patients treated with hemodialysis in Khorshid and Amin hospitals in Isfahan. The main researcher, all colleagues involved in data collection, laboratory and analyzer and the safety and monitoring committee are not aware of the assignment of subjects to the two intervention and control groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age > 18 years, patients with chronic hemodialysis for at least three months And consent to to participate in the study Exclusion criteria: Patients receiving warfarin, clopidogrel and being pregnant

##### Intervention groups

Intervention group: 44 participants will take an odorless garlic supplement for 8 weeks, which contains 500 mg of garlic powder and 2 mg allicin at each tablet (manufactured by Gol Daroo Company), two tablets daily ,after lunch. Control group: 44 participants will take placebo tablets containing starch and odorless (made by Gol Daroo company) for 8 weeks, two tablets daily, after lunch.

##### Main outcome variables

Dialysis adequacy; Serum albumin level; PTH level; calcium level; phosphorus level; CRP level; blood lipid profile in all participants (n = 88)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210825052286N1**

Registration date: **2021-10-17, 1400/07/25**

Registration timing: **prospective**

Last update: **2021-10-17, 1400/07/25**

Update count: **0**

##### Registration date

2021-10-17, 1400/07/25

##### Registrant information

##### Name

farzaneh fatahi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3625 6177

##### Email address

drfatahi79@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-22, 1400/09/01

##### Expected recruitment end date

2022-01-20, 1400/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Evaluation effect of garlic supplementation pill on dialysis adequacy , serum albumin, PTH, calcium, phosphorus, CRP levels and blood lipid profile in patients undergoing chronic hemodialysis in Khorshid and amin hospital (Esfahan)2020-2021

### Public title

Effect of garlic supplementation pill in dialyisic patient

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Chronic kidney Patients that undergoing hemodialysis for at least three months

#### Exclusion criteria:

Patients receiving warfarin, clopidogrel Being pregnant

### Age

From **18 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

### Sample size

Target sample size: **88**

### Randomization (investigator's opinion)

Randomized

### Randomization description

After collecting all the subjects (88 patients), they are divided into two groups of intervention (44 patients) and control (44 patients) by simple individual randomization using statistical software. In this process participants, researchers and questioners, sample takers and registrants, data importers and data analysts, as well as the Data Monitoring and Safety Committee are unaware of the type of this allocation.

### Blinding (investigator's opinion)

Triple blinded

### Blinding description

In the assignment stage : All subjects are divided into two intervention and control groups of 44 people without any knowledge in terms of allocation as well as questioners. In the blood sampling stage at pre- and post-intervention phase, the participant ,samplers, laboratory staff, questioners, and registrants of the results are not aware of the participants' assigned group. In the intervention stage: the intervention group is given a garlic supplement that is odorless and the control group is given control of placebo tablets containing starch that are odorless and have the same appearance as garlic tablets (from the same company). In the stage of data collection and analysis: Questioners, data

importers and analysts do not know the type of intervention and control group and the data is given to them in form of group 1 and group 2.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

##### Street address

Esfahan University of Medical Sciences, Hezar Jerib Street

##### City

Esfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2021-07-16, 1400/04/25

#### Ethics committee reference number

IR.MUI.MED.REC.1400.319

## Health conditions studied

### 1

#### Description of health condition studied

Chronic Kidney Disease

#### ICD-10 code

N18

#### ICD-10 code description

Chronic kidney disease (CKD)

## Primary outcomes

### 1

#### Description

serum albumin

#### Timepoint

before intervention and 8 weeks after intervention starts

#### Method of measurement

Blood sampling for serum albumin

### 2

#### Description

Serum PTH(Para Thyroid Hormone)

#### Timepoint

Before intervention and 8 weeks after intervention starts  
**Method of measurement**  
blood sampling for serum PTH

### 3

**Description**

Serum calcium

**Timepoint**

Before intervention and 8 weeks after intervention starts

**Method of measurement**

Blood sampling for serum calcium

### 4

**Description**

Serum phosphorus

**Timepoint**

Before intervention and 8 weeks after intervention starts

**Method of measurement**

Blood sampling for serum phosphorus

### 5

**Description**

serum CRP(C-Reactive Peptide)

**Timepoint**

Before intervention and 8 weeks after intervention starts

**Method of measurement**

Blood sampling for serum CRP(C-Reactive Peptide)

### 6

**Description**

Serum total cholesterol

**Timepoint**

Before intervention and 8 weeks after intervention starts

**Method of measurement**

Blood sampling for serum total cholesterol

### 7

**Description**

Serum Low Density Lipoprotein (LDL)

**Timepoint**

Before intervention and 8 weeks after intervention starts

**Method of measurement**

Blood sampling for serum Low Density Lipoprotein (LDL)

### 8

**Description**

Serum High Density Lipoprotein (HDL)

**Timepoint**

Before intervention and 8 weeks after intervention starts

**Method of measurement**

Blood sampling for serum High Density Lipoprotein (HDL)

### 9

**Description**

Serum triglyceride

**Timepoint**

Before intervention and 8 weeks after intervention starts

## **Method of measurement**

Blood sampling for serum triglyceride

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

**Description**

Intervention group: Garlic pill made by Gol Daroo Pharmaceutical Company, which is odorless and contains 500 mg of garlic t and 2 mg of allicin, two pills daily after lunch.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: Placebo tablets of Gol Daroo Pharmaceutical Company that contain starch and they are odorless and have the same appearance as garlic pills, two pills daily after lunch

**Category**

Placebo

## **Recruitment centers**

### 1

**Recruitment center**

**Name of recruitment center**

Khorshid hospital

**Full name of responsible person**

Sahar Vahdat

**Street address**

No 105 ,Ostandari Ave, Khorshid Hospital

**City**

Esfahan

**Province**

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**Postal code**

8174673461

**Phone**

+98 31 3222 2127

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nour@mui.ac.ir

**Web page address**

### 2

**Recruitment center**

**Name of recruitment center**

Amin Hospital

**Full name of responsible person**

Sahar Vahdat

**Street address**

AVE SINA Ave

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amin@mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Shaghayegh Haghjoo  
**Street address**  
Hezar -Jerib Ave  
**City**  
Esfahan  
**Province**  
Isfahan  
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8174673461  
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**Email**  
research@mui.ac.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**  
Farzaneh Fatahi  
**Position**  
Assistant  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**

Internal Medicine  
**Street address**  
No. 100, Farshadi Ave, Chahar Bagh Bala Ave  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
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## Person responsible for updating data

#### Contact

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assistant  
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**Province**  
Isfahan  
**Postal code**  
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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**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available