

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

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No 105 ,Ostandari Ave, Khorshid Hospital

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2

Recruitment center

Name of recruitment center

Amin Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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

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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