

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of Garlic tablet effects on Hemodialysis patients Inflammatory factors.

Protocol summary

Study aim

Determining the effect of garlic extract on the level of inflammatory factors in hemodialysis patients of the Dialysis Center of Bu Ali Sina Hospital of Qazvin in 1399

Design

Then patients were randomly selected using allocation random software

Settings and conduct

At first, in this double-blind clinical trial study, 54 eligible kidney failure patients referred to the dialysis center of Bu Ali Sina Hospital are checked. Patients registered in the form of a questionnaire. These patients are also undergoing blood sampling during routine monthly blood sampling by a dialysis nurse for tests. Sampling is done at 22 ccs when they are fasting, then samples are sent to a laboratory. Patients are randomly selected using allocation random software. Software is assigned in two groups (at the end of the proposal). Then garlic tablet is given to group A and placebo is given to group B. After two months, re-sampling is done to measure the intended factors. During the study, taking pills is followed by the facilitator by counting the pills and calling them.

Participants/Inclusion and exclusion criteria

Entry criteria: All patients with chronic renal failure related to hemodialysis. Having consented to participate in the project. Exclusion criteria: Patients with sensitivity to garlic. Existence of autoimmune diseases such as rheumatic diseases and chronic inflammatory diseases. History of corticosteroid use Anticoagulants. Patients with a history of glomerulonephritis as a cause of chronic renal failure.

Intervention groups

Hemodialysis patients

Main outcome variables

IL6 -ESR- CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200831048562N1**

Registration date: **2021-03-15, 1399/12/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-15, 1399/12/25**

Update count: **0**

Registration date

2021-03-15, 1399/12/25

Registrant information

Name

Freshteh Khanzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3368 4264

Email address

f.khanzadeh7@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-10, 1399/12/20

Expected recruitment end date

2021-05-10, 1400/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Garlic tablet effects on Hemodialysis patients Inflammatory factors.

Public title

Evaluating the effect of Garlic on dialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All ESRD patients who need hemodialysis (at least six months before dialysis starts)

Exclusion criteria:

Allergic to garlic patients Corticosteroids, Anticoagulants, and Statins using records Underlying autoimmune disease records on patients

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two treatment groups A and B using the balance block randomization method, the size of each block is 6 and the block quantity is 10. The method of balanced randomization allocation is used for participants in a randomized controlled clinical trial study to evaluate the effect of garlic tablets (group A) and placebo (group B) on quantitative variables (IL4 -ESR- CRP-BMI, calcium, phosphorus, Albumin, LDL-HDL-K-Na) is used.

Blinding (investigator's opinion)

Double blinded

Blinding description

The double-blind method is used for this study. The patients who have been studied are located in two groups of "intervention" & "control". The researcher and patient are blind regarding drugs and placebo usage.

Placebo

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Qazvin University of Medical Sciences

Street address

Minudar Street, Velaia Hospital

City

Qazvin

Province

Qazvin

Postal code

3415755570

Approval date

2020-08-09, 1399/05/19

Ethics committee reference number

IR.QUMS.REC.1399.145

Health conditions studied**1****Description of health condition studied**

Hemodialysis patients

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

Primary outcomes**1****Description**

CRP

Timepoint

At the beginning of the study and two months after intervention

Method of measurement

serum sample

2**Description**

ESR

Timepoint

At the beginning of the study and two months after intervention

Method of measurement

serum sample

3**Description**

IL6

Timepoint

At the beginning of the study and two months after intervention

Method of measurement

serum sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group A is given garlic tablets twice a day for two months

Category

Treatment - Drugs

2

Description

Control group: Group B placebo (without color and taste) is given twice a day for two months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dialysis Center of Bu Ali Sina Hospital, Qazvin

Full name of responsible person

Fereshteh khazadeh

Street address

2nd Floor, No. 11, Miaad Alley., Daneshgah St., Qazvin., Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mehdi Emam Jomee

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin University of Medical Sciences

Proportion provided by this source

50

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

Qazvin University of Medical Sciences

Full name of responsible person

Fereshteh khazadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Negar Sheikh davoodi

Position

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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