

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Effectiveness of oral administration of Allium sativum on lipid profile, inflammatory and cardiovascular indexes among hemodialysis patients

Protocol summary

Study aim

Determination of the efficacy of oral administration of Allium sativum on lipid profile, inflammatory and cardiovascular indexes in patients undergoing hemodialysis

Design

60 eligible patients undergoing hemodialysis; according to exclusion and inclusion criteria, were chosen purposefully and a code was allocated to each one of them. The patients were randomly divided into two group.

Settings and conduct

Study will be done in bolol rohani hospital dialysis center, according to balanced block randomization method, In intervention group, they received 400 mg of standard garlic powder extract tablets twice a day for 8 weeks, each tablet contains 1000 micrograms of allin.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age above 18; Exclusion criteria: Recent use of medicines and food containing garlic; history of garlic sensitivity; history of bleeding disorders; and the use of warfarin; history of ileal bypass; history of infection or admission during the past three months; unwillingness to participate in the research project and taking medication

Intervention groups

In intervention group, in addition to the standard treatment, patients received 400 mg of standard garlic powder extract tablets twice a day for 8 weeks. each tablet contains 1000 micrograms of alliin. In the control group, a placebo was prescribed during this period.

Main outcome variables

Lipid profile, inflammatory and cardiovascular indicators, IL6, CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170725035305N2**

Registration date: **2018-01-21, 1396/11/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-21, 1396/11/01**

Update count: **0**

Registration date

2018-01-21, 1396/11/01

Registrant information

Name

Amirhesam Alirezaei

Name of organization / entity

Shahid Beheshti University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 21 2208 3095

Email address

aalirezaei@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2019-04-19, 1398/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of oral administration of Allium sativum on lipid profile, inflammatory and cardiovascular indexes

among hemodialysis patients

Public title
Efficacy of oral administration of Allium sativum on lipid profile, inflammatory and cardiovascular indexes among hemodialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years 6 month after initiation of hemodialysis
Exclusion criteria:
Recent use of medicines and foods that contain garlic
Sensitivity to garlic
History of bleeding
History of infection or hospitalization in the past 3 month
History of warfarin use
History of ileal bypass

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The qualified patients were divided into intervention and control groups (each group consisted of half the patients) according to balanced block randomization method.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients and the investigator won't receive information on which type of treatment and which individual will receive the placebo or treatment.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

7th Floor, Bldg No.2 , hahid Beheshti University of

Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, chamran highway, Tehran, Iran.

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Postal code

19839-63113

Approval date

2017-10-28, 1396/08/06

Ethics committee reference number

IR.SBMU.RETECH.REC.1396.548

Health conditions studied

1

Description of health condition studied

Renal Hemodyalisis

ICD-10 code

Z99.2

ICD-10 code description

Dependence on renal dialysis

Primary outcomes

1

Description

Lipid profile

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

2

Description

IL6

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

3

Description

ESR

Timepoint

Before and after intervention

Method of measurement

Laboratory

4

Description

Homocysteine

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, patients received 400 mg of standard garlic powder extract tablets twice a day for 8 weeks. each tablet contains 1000 micrograms of alliin. The drug was produced by the Amin pharmaceutical company.

Category

Treatment - Drugs

2

Description

Control group: The placebo was prescribed. The placebo was completely similar to the original drug and it was made of starch. Patients will receive placebo tablets twice a day for 8 weeks. The drug was produced by the Amin pharmaceutical company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rohani Hospital, Dialysis Center

Full name of responsible person

Amirhesam Alirezaei

Street address

Ayatollah Rohani Hospital, Ganjafruz Street, Babol, Mazandaran province

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Postal code

Phone

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2

Recruitment center

Name of recruitment center

Shahid Moddares Hospital, Dialysis Center

Full name of responsible person

Amirhesam Alirezaei

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Shahid Modarres Hospital, Saadat Abad Blvd., Yadegar Emam Highway, Tehran

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http://modarres.sbm.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ali Ziaei

Street address

7th Floor, Bldg No.2 , Shahid Beheshti University of Medical Sciences, Arabi Ave., Daneshjoo Blvd., Velenjak, Chamran Highway, Tehran, Iran

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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

Shahid beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amirhesam Alirezaei

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Will be shared after data collection

When the data will become available and for how long

2017 December until april 2018

To whom data/document is available

Researchers

Under which criteria data/document could be used

For further evaluation and research

From where data/document is obtainable

Amirhesam alirezaei

What processes are involved for a request to access data/document

After requesting by email and explaining the purpose of the requesting party, Information will be provided to them.

Comments