

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Efficacy of oral administration of Allium sativum on lipid profile, inflammatory indexes, function and structure of peritoneal membrane in patients on peritoneal dialysis

Protocol summary

Summary

Among 46 patients undergoing peritoneal dialysis who referred to Shafa Dialysis Center, according to inclusion & exclusion criteria, 40 eligible patients were chosen. The patients participated in the study consciously and arbitrarily and they were chosen with respect to ethics confirmed by the hospital ethic committee and were enrolled in RCT Bank. The qualified patients were divided into intervention and control groups (each group consisted of 20 people) according to balanced block randomization method. 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. Lipid profile, inflammatory and cardiovascular indicators and peritoneal function tests were evaluated in each group before and after intervention. Patients were monitored for any complications, side effects and drug safety in each follow up visits. Anonymously collected demographic data includes age, sex, history of diabetes, history of hypertension, lipid profile, underlying disorders leading to renal failure, duration of the disease, duration of peritoneal dialysis, drug history and inflammatory and cardiovascular indicators. Statistical analysis will be performed by SPSS 19 software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017072535305N1**

Registration date: **2017-10-16, 1396/07/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-16, 1396/07/24

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

Shahid Modarres Hospital Clinical Research Center, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of oral administration of Allium sativum on lipid profile, inflammatory indexes, function and structure of peritoneal membrane in patients on peritoneal dialysis

Public title

Efficacy of oral administration of Allium sativum on lipid

profile, inflammatory indexes, function and structure of peritoneal membrane in patients on peritoneal dialysis

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion criteria : Recent use of medicines and foods that contain garlic; sensitivity to garlic; history of bleeding; disorders and use of warfarin; history of infection or hospitalization in the last 3 months; unwillingness to continue to participate in the research project; history of gastric bypass; do not use more than 80% of medicine. Inclusion criteria : age above 18; six months have passed since the onset of peritoneal dialysis.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid modarres hospital

Street address

Shahid Beheshti University of Medical Sciences

City

Tehran

Postal code

Approval date

2017-05-16, 1396/02/26

Ethics committee reference number

IR.SBMU.MSP.REC.1396.114

Health conditions studied

1

Description of health condition studied

Z49.2

ICD-10 code

Z49.2

ICD-10 code description

Other dialysis

Primary outcomes

1

Description

Lipid profil, TG, CHOL, HDL, LDL in control group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

2

Description

IL6 in control group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

3

Description

ESR in control group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

4

Description

Albumin in control group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

5

Description

CRP in control group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

6

Description

Ferritin in control group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

7

Description

Homocysteine in control group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

8

Description

CBC.diff in control group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

9

Description

Serum iron in control group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

10

Description

Peritoneal equilibration test in control group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

11

Description

Blood pressure in control group

Timepoint

Before and after intervention

Method of measurement

Sphygmomanometer

12

Description

Weight in control group

Timepoint

Before and after intervention

Method of measurement

Scale

13

Description

ASt in control group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

14

Description

ALT in control group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

15

Description

Lipid profil,TG.CHOL.HDL.LDL

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

16

Description

IL6 in case group in cases group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

17

Description

ESR in cas3 group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

18

Description

Albumin in case group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

19

Description

CRP in case group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

20

Description

Ferritin Fein case group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

21

Description

Homocysteine in case group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

22

Description

CBC.diff in case group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

23

Description

Serum iron in case group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

24

Description

Peritoneal equilibration test in case group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

25

Description

Blood pressure Blin case group

Timepoint

Before and after intervention

Method of measurement

Sphygmomanometer

26

Description

Weight in case group

Timepoint

Before and after intervention

Method of measurement

Scale

27

Description

AST in case group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

28

Description

ALT in case group

Timepoint

Before and after intervention

Method of measurement

Laboratory measurement

Secondary outcomes

empty

Intervention groups

1

Description

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

In the control group, The placebo was prescribed. The placebo was completely similar to the original drug and it was made of starch. and it also The drug was produced by the Amin pharmaceutical company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafaa Dialysis Center

Full name of responsible person

Amirhesam Alirezaei

Street address

Shafaa Dialysis Center, Farhang hosseini street, Taleghani, Valiasr street , Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Modarres Clinical Research Center, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amirhesam alirezaei

Street address

Shahid Modarres Hospital, Sa'adat abad, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Modarres Clinical Research Center, Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amirhesam Alirezaei

Position

Nephrologist

Other areas of specialty/work

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran. Post Code: 19839-6311

City

Tehran

Postal code

Phone

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Fax

Email

Amirhesam124@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Modarres Hospital, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amirhesam Alirezaei

Position

Nephrologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University Of Medical Sciences

Full name of responsible person

Amirhesam Alirezaei

Position

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Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty