

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the efficiency of alpha-lipoic acid supplementation on inflammatory biomarkers in hemodialysis patients: A double-blind placebo clinical trial

Protocol summary

Study aim

Evaluating the efficiency of alpha-lipoic acid supplementation on inflammatory biomarkers in hemodialysis patients:

Design

A parallel-group placebo-controlled double-blind, randomized controlled trial on 96 patients using simple randomization

Settings and conduct

In this study, patients (20-80 yr.) with a history of hemodialysis treatment for at least six months prior to enrollment will be recruited by board-certified nephrologists at the dialysis ward of the Hajar Hospital - an affiliated medical center with the Shahr-e-Kord University of Medical Sciences in Iran. After providing written constants, patients will be enrolled according to a-priori defined inclusion and exclusion criteria and randomized to two (intervention and control) groups with a sample size of n=46 in each group. The intervention group will receive alpha-lipoic acid supplements with a dose of 300 mg/day, whereas the control group will consume placebo capsules filled with wheat flour. The duration of the study will be for eight weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Patients (20-80 yr.) with a history of hemodialysis treatment for a minimum of six months and willing to participate in the trial Exclusion criteria: - Any recent changes in patients' lifestyle behaviors (dietary regimen, physical activity, stress) - History of consuming any antioxidant or anti-inflammatory dietary supplements less than one month before study enrollment - Possible kidney transplantation - History of alcohol consumption or cigarette smoking - Allergies or intolerance to alpha-lipoic acid - History of cancer

Intervention groups

The intervention group will receive alpha-lipoic acid with doses of 300 mg/day.

Main outcome variables

Tumor necrosis factor alpha Interleukin-6 Irisin Total antioxidant capacity Blood Urea Nitrogen Creatinine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160206026390N12**

Registration date: **2020-12-23, 1399/10/03**

Registration timing: **retrospective**

Last update: **2020-12-23, 1399/10/03**

Update count: **0**

Registration date

2020-12-23, 1399/10/03

Registrant information

Name

Ehsan Ghaedi

Name of organization / entity

Ahwaz Jundishapoor ,University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3285

Email address

ghaedi.e@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

2017-09-23, 1396/07/01

Actual recruitment end date

2017-12-21, 1396/09/30

Trial completion date

2018-01-10, 1396/10/20

Scientific title

Evaluating the efficiency of alpha-lipoic acid supplementation on inflammatory biomarkers in hemodialysis patients: A double-blind placebo clinical trial

Public title

Effects of alpha-lipoic acid on patients undergoing hemodialysis

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients (20-80 yr.) with a history of hemodialysis treatment for a minimum of six months Willing to participate in the trial

Exclusion criteria:

- Any recent significant changes in patients' lifestyle behaviors (diet, physical activity, stress) - History of consuming any antioxidant or anti-inflammatory dietary supplements less than one month before study enrollment - Possible kidney transplantation - History of alcohol consumption - History of cigarette smoking - Allergies or intolerance to alpha-lipoic acid - History of cancer

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **92**

Actual sample size reached: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be carried out using a parallel design. Allocation concealment will be maintained by sealed envelopes during the trial. Participants selected a single envelope among identical sealed envelopes, wherein their assignment groups were included.

Blinding (investigator's opinion)

Double blinded

Blinding description

All placebo and alpha-lipoic acid capsules were in the same color and in the same containers. Nephrologist, investigator, and patients were uninformed about allocation. Only one of the personnel was informed about

allocation.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Shahrekord University of Medical Sciences

Street address

Rahmatieh, Shahrekord University of Medical Sciences

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816754633

Approval date

2016-11-27, 1395/09/07

Ethics committee reference number

IR.SKUMS.REC.1395.206

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

Patient undergoing hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

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

Total Antioxidant Capacity

Timepoint

Before and after study

Method of measurement

Laboratory kits

2**Description**

Tumor necrosis factor- alpha

Timepoint

Before and after study

Method of measurement

Laboratory kits

3

Description

Erythroblast Sedimentation Rate

Timepoint

Before and after study

Method of measurement

Laboratory kits

4

Description

Interleukin - 6

Timepoint

Before and after study

Method of measurement

Laboratory kits

5

Description

c-reactive Protein

Timepoint

Before and after study

Method of measurement

Laboratory kits

6

Description

Irisin

Timepoint

Before and after study

Method of measurement

Laboratory kits

Secondary outcomes

1

Description

weight

Timepoint

Before and after Study

Method of measurement

Sensitive Balance

Intervention groups

1

Description

The intervention group will receive alpha-lipoic acid supplements with a dose of 300 mg/day, The duration of the study will be for eight weeks.

Category

Treatment - Other

2

Description

The control group will consume placebo capsules filled with wheat flour. The duration of the study will be for

eight weeks.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Hajar Hospital

Full name of responsible person

Parisa Javadian

Street address

Nurse st. Hajar Hospital

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

-

Phone

+98 38 3222 0016

Email

ehsanghaedi073@gmail.com

Web page address

<https://hajarhp.skums.ac.ir/>

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahrekord University of Medical Sciences

Full name of responsible person

Seyed Kamal Solati

Street address

Rahmatieh, Shahrekord University of Medical Sciences

City

ShahreKord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 3333 0061

Email

info@skums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahrekord 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
Shahrekord University of Medical Sciences
Full name of responsible person
Parisa Javadian
Position
Nephrologist
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Nurse st. Hajar Hospital
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3222 0016
Fax
Email
javadianp@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hajar Hospital Research Center
Full name of responsible person
Ehsan Ghaedi
Position
Nutritionist
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Hajar Hospital, Research Center
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713471
Phone
+98 38 3225 2416
Fax
Email
ehsanghaedi073@gmail.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Hajar Hospital Research Center
Full name of responsible person
Ehsan Ghaedi
Position
Nutritionist
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Hajar Hospital Research Center
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3225 2416
Fax
Email
ehsanghaedi073@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
"There is no further information"
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