Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 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)

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+98 61 3374 3285

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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
Befor 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

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Nurse st. Hajar Hospital

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javadianp@gmail.com

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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

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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