Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of Alfa lipoic acid, Vitamin E supplementation and their combination on oxidative stress, lipid profile, insulin resistance, inflammation and nutritional status in patients on hemodialysis, Shiraz, 2010

Protocol summary

Summary
To evaluate the effect of Vitamin E, lipoic acid (LA) and their combination on long term complications in patients on hemodialysis, 96 hemodialysis patients, aged 20-60 years old, were recruited from Sadra and Namazi dialysis centers in Shiraz, Iran. The patients were randomly assigned into the following 4 groups, based on the block randomization protocol, to receive 600 mg LA, 400IU Vitamin E, 600mg LA+400IU Vitamin E, daily, or placebo for 2 months. Primary outcome of this study is evaluation of oxidative stress through measurement of hs-CRP, MDA, and IL6.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT201103156072N1**
Registration date: **2011-04-15, 1390/01/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2011-04-15, 1390/01/26

Registrant information
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Recruitment status
Recruitment complete

Funding source
Shiraz University of Medical Sciences

Expected recruitment start date
2011-01-10, 1389/10/20
Expected recruitment end date
2011-03-01, 1389/12/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Alfa lipoic acid, Vitamin E supplementation and their combination on oxidative stress, lipid profile, insulin resistance, inflammation and nutritional status in patients on hemodialysis, Shiraz, 2010

Public title
Evaluation of the effect of Alfa lipoic acid, Vitamin E supplementation and their combination on long term complications in patients on hemodialysis, Shiraz, 2010
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: age 20-60 years, hemodialysis, twice a week, undergoing maintenance hemodialysis for more than 1 year, no receiving antioxidant supplements such as VitE, VitC, or fish oil Exclusion criteria: smoking, pregnancy, presence of acute inflammatory and

infectious diseases, presence of liver or Rheumatic diseases (such as lupus,...), cardiac diseases, or cancer, use of anticoagulants or contraceptives thyroxin

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences

City
Shiraz

Postal code

Approval date
2011-01-06, 1389/10/16

Ethics committee reference number
89-5408

Health conditions studied

1

Description of health condition studied
End stage of renal disease (hemodialysis)

ICD-10 code
N18

ICD-10 code description
Chronic renal failure

Primary outcomes

1

Description
hs-CRP

Timepoint
Before and 2 months after intervention

Method of measurement
ELISA kit

2

Description
malon-dialdehide (MDA)

Timepoint
Before and 2 months after intervention

Method of measurement
Spectrophotometry

3

Description
Interlukin-6 (IL6)

Timepoint
Before and 2 months after intervention

Method of measurement
RIA

Secondary outcomes

1

Description
insulin

Timepoint
Before and 2 months after intervention

Method of measurement
ELISA kit

2

Description
lipid profile

Timepoint
Before and 2 months after intervention

Method of measurement
Auto analyser

3

Description
FBS

Timepoint
Before and 2 months after intervention

Method of measurement
Auto analyser

Intervention groups

1

Description
alpha-lipoic acid intake ,600mg per day, for 2 months

Category

Treatment - Drugs

2

Description
Vitamin E intake, 400IU per day ,for 2 months
Category
Treatment - Drugs

3

Description
alph-lipoic acid 600mg+VitaminE400IU, per day,for 2 months
Category
Treatment - Drugs

4

Description
placebo intake for 2 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sadra Hemodialysis Center
Full name of responsible person
Street address
City
Shiraz

2

Recruitment center
Name of recruitment center
Namazi Hemodialysis Center
Full name of responsible person
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Afsaneh Ahmadi
Street address
Shiraz University of Medical Sciences
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
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Person responsible for updating data

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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