

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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

Name

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Name of organization / entity

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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-dialdehyde (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

Name of organization / entity

School of Health And Nutrition, Shiraz University of
Mediccal Sciences

Full name of responsible person

Negin Mazouji

Position

MSc. student of nutrition

Other areas of specialty/work

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Other areas of specialty/work

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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