Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparative Effects of Silymarin and Vitamin E Supplementation on Oxidative Stress Markers, Lipid Profiles and Hemoglobin Level in Hemodialysis Patients

Protocol summary

Summary

Introduction and Background: The incidence of atherosclerosis among hemodialysis patients is very high. A considerable proportion of hemodialysis patients lack traditional risk factors of atherosclerosis. Oxidative stress is considered a major factor in morbidity and mortality among them. Objectives: Evaluating the effects of dietary supplementation with Silymarin and/or vitamin E on oxidative stress markers, lipid profile, and hemoglobin level in hemodialysis patientsa. Design: Eighty hemodialysis patients were randomized into 4 groups: Group 1 received Silymarin 140 mg three times daily; Group 2 received Vitamin E 400 IU/day; Group 3 received Silymarin 140 mg three times daily and Vitamin E 400 IU/day; Group 4 was the control. The duration of the study was 3 weeks. Vitamin E was administered as 400 mg pills. Setting and Conduct: Samples were obtained at baseline and on day 21 for measurement of malondialdehyde (MDA), RBC glutathione peroxidase (GPX), hemoglobin and lipid profiles. Fasting blood samples (10 ml) were collected in EDTA-containing tubes from the arterial line immediately before a mid week dialysis session, before heparin administration, and immediately before supplementation (baseline) and on day 21 after the intervention period. Samples were immediately centrifuged and frozen at −70°C. Participants including major eligibility criteria: Subjects were recruited from among clinically stable hemodialysis patients (age range 18–60 years) in Ebrahimi Hemodialysis Center in Sadra City (Shiraz, Iran). All patients received four hour hemodialysis treatments, three times per week. The membrane and the general dialysis prescription were similar for all patients. Exclusion criteria consisted of history of a cardiovascular event within the previous 12 months, use of cholesterol-lowering agents (statins), Omega-3, Vitamin E, levothyroxin, and oral contraceptives. Patients with any active infection including hepatitis B or C, New York Heart Association class III and IV heart failure were also excluded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904234376N1**
Registration date: **2010-08-24, 1389/06/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-08-24, 1389/06/02

Registrant information

Name

Bahram Shahriyari

Name of organization / entity

Shiraz Nephro-Urology Research Centre(SNURC)

Country

Iran (Islamic Republic of)

Phone

+98 71 1235 1086

Email address

shahriyari@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

This study was financially supported by Office of Vice Chancellor for Research, Shiraz University of Medical Sciences

Expected recruitment start date

2009-11-03, 1388/08/12

Expected recruitment end date

2010-03-11, 1388/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative Effects of Silymarin and Vitamin E Supplementation on Oxidative Stress Markers, Lipid Profiles and Hemoglobin Level in Hemodialysis Patients

Public title
Evaluation of the Effect of Silymarin, an Antioxidant, on Oxidative Stress Markers in Hemodialysis Patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Clinically stable patients within the age range of 18-60. Undergoing maintenance hemodialysis initiated >=3 months previously at a rate of 3 times per week, each session 4 hours. Exclusion criteria: History of cardiovascular event within the previous 12 months, use of cholestrol-lowering agents(statins), Omega-3, Vitamin E, Levothyroxin, and oral contraceptive pills (OCP), infections including HBV, HCV, heart failure class III and IV according to New York Heart Association(NYHA) were also excluded.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

1

Registry name
Clinicaltrials.gov

Secondary trial Id
NCT01001845

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Zand street-Central Building of Shiraz University of Medical Sciences

City
Shiraz

Postal code
1978-71345

Approval date
2009-12-11, 1388/09/20

Ethics committee reference number
ct-88-4821

Health conditions studied

1

Description of health condition studied
End Stage Renal Disease

ICD-10 code
N18.0

ICD-10 code description
End-stage renal disease

Primary outcomes

1

Description
Hemoglobin level

Timepoint
21 days

Method of measurement
Sampling and Biochemical Analysis

2

Description
Oxidative Stress Markers level

Timepoint
21 days

Method of measurement
Sampling and Biochemical Analysis

Secondary outcomes

empty

Intervention groups

1

Description
Silymarin and Vitamin E

Category

Treatment - Drugs

2

Description
Control: No study related intervention
Category
N/A

3

Description
Silymarin
Category
Treatment - Drugs

4

Description
Vitamin E
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Haj Ebrahimi dialysis centre-sadra
Full name of responsible person
Bahram Shahriyari
Street address
Haj Ebrahimi Dialysis Centre - Sadra City
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mohammad Hossein Dabaghmanesh
Full name of responsible person
Office of Vice Chancellor-Shiraz University of Medical Sciences
Street address
Central building of shiraz university of medical sciences-Zand street
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mohammad Hossein Dabaghmanesh
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
Shiraz Nephrology-Urology Research Centre
Full name of responsible person
Bahram Shahriyari
Position
Internist and fellow of Nephrology
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Person responsible for updating data

Contact

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Position
Internist and Fellow of Nephrology

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