

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the effect of vitamin E fortified whey drink on nutritional status, inflammatory markers and oxidative stress in hemodialysis patients

Protocol summary

Summary

The aim of this study is to evaluate the effect of vitamin E fortified whey drink on nutritional status, inflammatory markers and oxidative stress in hemodialysis patients. 92 hemodialysis patients will be selected for the study. Inclusion criteria: mean age of 17-65 years old; having mild, moderate or severe malnutrition based on the SGA (subjective global assessment) assessment; be dialyzed at least 2 times a week for 3 months. Exclusion criteria: hospitalization in the last month; active infection; using immunosuppressant drugs or multi-vitamins; pregnancy. Weight and height of the patients will be recorded for BMI (body mass index) calculation. Informed consent will be signed by all of them for participating in the study. Then, all of the patients will be divided into 4 groups: 1- consumption of 230 milliliters of whey drink three times a week, 2-consumption of 230 milliliters of whey drink fortified with 400 milligrams of vitamin E three times a week, 3-consumption of 400 milligrams of vitamin E three times a week, 4- control group: no intervention, Patients will be followed for 2 months. At the beginning and the end of the 2-month intervention period, 10 milliliters of blood will be taken from all of the patients and nutritional status of the patients will be assessed as the primary outcome. Serum levels of malondialdehyde, c-reactive protein, albumin, transferrin and lipoproteins will be measured. SGA, MIS and SF-12 questionnaires will be filled for all of the patients at the beginning and the end of the study.

General information

Acronym

EVEWD

IRCT registration information

IRCT registration number: **IRCT201312132480N4**

Registration date: **2013-12-28, 1392/10/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-28, 1392/10/07

Registrant information

Name

Mohammad Hassan Eftekhari

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1725 1001

Email address

eftekharim@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of vitamin E fortified whey drink on nutritional status, inflammatory markers and oxidative stress in hemodialysis patients

Public title

Evaluating the effect of vitamin E fortified whey drink on nutritional status, inflammatory markers and oxidative stress in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: mean age of 17-65 years old; having mild, moderate or severe malnutrition based on the SGA (subjective global assessment) assessment; be dialyzed at least 2 times a week for 3 months. Exclusion criteria: hospitalization in the last month; active infection; using immunosuppressant drugs or multi-vitamins; pregnancy.

Age

From **17 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not 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**

2012-09-22, 1391/07/01

Ethics committee reference number

91-6424

2**Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences

City

Shiraz

Postal code**Approval date**

2010-08-20, 1389/05/29

Ethics committee reference number

91-6424

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

Hemodialysis

ICD-10 code

Z49.1

ICD-10 code description

Extracorporeal dialysis

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

Malnutrition

Timepoint

2 months

Method of measurement

SGA assessment

2**Description**

Malnutrition

Timepoint

2 months

Method of measurement

SGA assessment

Secondary outcomes**1****Description**

Serum levels of malondialdehyde

Timepoint

2 months

Method of measurement

TBA method (biochemical)

2**Description**

Serum levels of c-reactive protein

Timepoint

2 months

Method of measurement

ELISA kit

3

Description

serum transferrin

Timepoint

2-months

Method of measurement

autoanalyzer

4

Description

Serum levels of albumin

Timepoint

2-months

Method of measurement

autoanalyzer

5

Description

serum lipoproteins

Timepoint

2-months

Method of measurement

autoanalyzer

6

Description

Subjective Global Assessment

Timepoint

2-months

Method of measurement

Questionnaire

7

Description

quality of life

Timepoint

2-months

Method of measurement

SF-12 questionnaire

8

Description

MIS

Timepoint

2-months

Method of measurement

Questionnaire

9

Description

weight

Timepoint

2-months

Method of measurement

scale

Intervention groups

1

Description

Consumption of 230 milliliters of whey drink three times a week

Category

Treatment - Other

2

Description

Consumption of 230 milliliters of whey drink fortified with 400 milligrams of vitamin E three times a week

Category

Treatment - Other

3

Description

Control group: no intervention

Category

N/A

4

Description

Consumption of 400 milligrams of vitamin E three times a week

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shahid Faghihi and Namazi hospitals, Dialysis centers of Shiraz University of Medical Sciences

Full name of responsible person**Street address****City**

Shiraz

2

Recruitment center**Name of recruitment center**

Shahid Faghihi and Namazi hospitals, Dialysis centers of Shiraz University of Medical Sciences

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
Dr Postforosh

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

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

2

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr Postforosh

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

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 university of medical sciences

Full name of responsible person
Zahra Sohrabi

Position
PhD Candidate

Other areas of specialty/work

Street address
Mehr Building, Lane 4/A, Iman Jonobi Avenue, Shiraz, Iran

City
Shiraz

Postal code
00989177113086

Phone
+98 917 711 3086

Fax

Email
Zahra_2043@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr Mohammad Hassan Eftekhari

Position
Associate Professor

Other areas of specialty/work

Street address
Razi Avenue, School of Nutrition and Food Science, Shiraz University of Medical Sciences, Shiraz, Iran

City
Shiraz

Postal code

Phone
+98 917 708 8717

Fax

Email
h_eftekhari@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Zahra Sohrabi

Position
PhD candidate

Other areas of specialty/work

Street address
Mehr Building, Lane 4/A, Iman Jonobi Avenue, Shiraz, Iran

City
Shiraz

Postal code

Phone
+98 917 711 3086

Fax

Email
Zahra_2043@yahoo.com

Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>