Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Dark Chocolate Consumption on Serum Levels of Lipoprotein(a), Apolipoprotein A-1, Apolipoprotein B, Inflammatory Markers, Oxidative Stress, lipid profile, health-related quality of life and symptoms of anxiety and depression in Hemodialysis Patients

Protocol summary

Study aim

Determining and comparing the mean Lp(a), Apo A-1,Apo B, MDA, IL-6, anthropometric indices (weight, body mass index, waist circumference), blood pressure, depression score, anxiety score, quality of life score, lipid profile, the correlation between changes in lipid profile indices and changes in mental health scores between the dark chocolate recipient group and the control group at the end of the study, and within each group between the beginning and end of the study.

Design

Allocation of participants to the intervention and control groups in this study will be performed using randomized block permutation method with the blockrand package in the R programming environment. The sample size was determined based on the ANCOVA model using G*Power software.

Settings and conduct

The intervention of this study involves the consumption of 50 grams of 83% dark chocolate produced by Farmand Food Industries Company. This product is offered in 25-gram packages, and patients will receive two packages (totaling 50 grams) in each hemodialysis session, to be consumed during the last hour of dialysis under the supervision of the researcher or the ward nurse to ensure full protocol compliance. Study location: Dialysis departments of Firouzgar Hospital and Hashemi Nejad Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Hemodialysis patients with at least three months of hemodialysis history, without any other acute diseases.

Intervention groups

Intervention group: The group receiving 50 grams of 83% dark chocolate for eight weeks on hemodialysis days (3 times a week), along with specialized nutritional counseling for dialysis patients. Control group: The control group that receives specialized nutritional counseling for dialysis patients and continues only their routine care.

Main outcome variables

Lipoprotein a; Apo A-1; Apo B; IL-6; MDA

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091114002709N68**
Registration date: **2026-03-31, 1405/01/11**
Registration timing: **prospective**

Last update: **2026-03-31, 1405/01/11**
Update count: **0**

Registration date

2026-03-31, 1405/01/11

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8862 2755

Email address

shidfar.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-04-21, 1405/02/01

Expected recruitment end date

2026-09-22, 1405/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Dark Chocolate Consumption on Serum Levels of Lipoprotein(a), Apolipoprotein A-1, Apolipoprotein B, Inflammatory Markers, Oxidative Stress, lipid profile, health-related quality of life and symptoms of anxiety and depression in Hemodialysis Patients

Public title

The Effect of Dark Chocolate Consumption on Serum Levels of Lipoprotein(a), Apolipoprotein A-1, Apolipoprotein B, Inflammatory Markers, Oxidative Stress, lipid profile, health-related quality of life and symptoms of anxiety and depression in Hemodialysis Patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patient's consent to participate in the study and signify informed consent form The number of hemodialysis three times per week At least three months of history of hemodialysis BMI>30

Exclusion criteria:

Active infectious diseases including hepatitis and malignancies Allergy or intolerance to dark chocolate in the intervention group Regular consumption of dark chocolate in the daily diet Being on the threshold of kidney transplantation Consumption of antioxidant supplements or similar herbal products in the past 3 months

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be allocated to the intervention and control groups in this study using the randomized block method with the blockrand package in the R programming environment. The main goal of employing this method is to maintain balance in the number of individuals in each group during the data collection process and prevent imbalances resulting from the timing of participant recruitment. In the randomized block method, allocation occurs in consecutive blocks; such that in each block, an equal number of individuals are assigned to the intervention and control groups. In this study, a block size of 4 has been selected; meaning that in each block, two individuals are assigned to the intervention group (A) and two to the control group (B). The order of individuals within each block is determined randomly to reduce the predictability of the allocation pattern.

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

Ethic Committee School of Health, Iran University of Medical Sciences

Street address

Arjantin Square, Alvand Street, School of Health, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1516846514

Approval date

2026-01-26, 1404/11/06

Ethics committee reference number

IR.IUMS.SPH.REC.1404.020

Health conditions studied

1

Description of health condition studied

Hemodialysis patients

ICD-10 code

Z99.2

ICD-10 code description

Dependence on renal dialysis

Primary outcomes

1

Description

Lipoprotein (a)

Timepoint

The beginning of the study (before the start of the intervention), the end of the study (8 weeks after the start of the intervention)

Method of measurement

Immunoturbidometric method

Secondary outcomes

1

Description

Apolipoprotein A-1

Timepoint

The beginning of the study (before the start of intervention), the end of the study (8 weeks after the start of the intervention)

Method of measurement

Immunoturbidometric method

2

Description

Apolipoprotein B

Timepoint

The beginning of the study (before the start of intervention), the end of the study (8 weeks after the start of the intervention)

Method of measurement

Immunoturbidometric method

3

Description

Inflammatory factor IL-6

Timepoint

The beginning of the study (before the start of intervention), the end of the study (8 weeks after the start of the intervention)

Method of measurement

ELISA test

4

Description

MDA

Timepoint

The beginning of the study (before the start of intervention), the end of the study (8 weeks after the start of the intervention)

Method of measurement

ELISA test

5

Description

Lipid profile

Timepoint

The beginning of the study (before the start of intervention), the end of the study (8 weeks after the start of the intervention)

Method of measurement

TG, HDL-C and TC concentrations will be measured calorimetrically and LDL-C concentrations will be calculated using the Friedwald formula. .LDL-C (mg/dL) = TC (mg/dL) − HDL-C (mg/dL) – (TG (mg/dL)/5)

6

Description

Anxiety and depression score

Timepoint

The beginning of the study (before the start of intervention), the end of the study (8 weeks after the start of the intervention)

Method of measurement

Hospital Anxiety and Depression Scale questionnaire

7

Description

health-related quality of life score

Timepoint

The beginning of the study (before the start of intervention), the end of the study (8 weeks after the start of the intervention)

Method of measurement

Kidney Disease Quality of Life-36 questionnaire

8

Description

Blood pressure

Timepoint

The beginning of the study (before the start of intervention), the end of the study (8 weeks after the start of the intervention)

Method of measurement

Digital blood pressure monitor

9

Description

Anthropometric indices

Timepoint

The beginning of the study (before the start of intervention), the end of the study (8 weeks after the start of the intervention)

Method of measurement

Standard meter and scale

Intervention groups

1

Description

Intervention group: Patients undergoing hemodialysis who will receive a specified amount of dark chocolate daily for a specified duration, in addition to their usual diet.

Category

Lifestyle

2

Description

Control group: Eligible hemodialysis patients who are

randomly assigned to the control group and, throughout the study period, will follow only their usual diet without receiving dark chocolate.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Hasheminejad hospital

Full name of responsible person
Dr.Shahrzad Ossareh

Street address
Vali Asr Street (AJ), above Vanak Square, Shahid Valinejad Alley, Shahid Hashminejad Hospital

City
Tehran

Province
Tehran

Postal code
1969714713

Phone
+98 21 81161

Email
hkciums1403@gmail.com

2

Recruitment center

Name of recruitment center
Firoozgar hospital

Full name of responsible person
Farahnaz Dadras

Street address
Vali Asr Square, Behafarin Street, Firoozgar hospital

City
Tehran

Province
Tehran

Postal code
1593748711

Phone
+98 21 8214 1000

Email
firoozgarhospital1@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Dr. Farzad Shidfar

Street address
Tehran Hemmat Highway next to Milad Tower

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8670 1021

Email
farzadshidfar@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Farzad Shidfar

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
School of Health, Iran University of Medical Sciences, Shahid Hemmat highway

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 8862 2755

Fax
+98 21 8862 2533

Email
shidfar.f@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Farzad shidfar
Position
professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Shahid hemmat expressway
City
Tehran
Province
Tehran
Postal code
1449614525
Phone
+98 21 8860 2218
Fax
+98 21 8860 2219
Email
farzadshidfar@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Farzad Shidfar
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
School of Health, Iran University of Medical Sciences, Shahid Hemmat highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8862 2755
Fax
+98 21 8862 2533
Email
shidfar.f@iums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Data related to study outcomes at the end of the study can be shared.
When the data will become available and for how long
The access period will be 6 months after publication.
To whom data/document is available
Researchers employed in academic and scientific institutions.
Under which criteria data/document could be used
For the purpose of using the data to conduct another study and apply it to patients.
From where data/document is obtainable
Name and surname: Dr. Farzad Shidfar Email address: shidfar.f@iums.ac.ir
What processes are involved for a request to access data/document
Request via email along with providing complete explanations regarding the reason for needing the data.
Comments