Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 2026

Effect of Synbiotic Dessert Fortified with Vitamin D and Calcium on Nutritional Indices, Inflammation, Oxidative stress, Malnutrition and Quality of Life in Hemodialysis Patients

Protocol summary

Study aim

Effects of synbiotic dessert fortified with vitamin D and calcium on nutritional biomarkers, inflammation, oxidative stress, state of malnutrition and quality of life in hemodialysis patients, in order to reduce the complications of chemical drugs and improve their quality of life

Design

Randomized parallel clinical trial with two groups of control and intervention with a sample size of 42

Settings and conduct

Hemodialysis patients in Namazi and Shahid Faghihi hospital at shiraz. with satisfaction of patients and under the supervision of the doctor, the intervention begins for eight weeks. Patients do the blood test for the examination considerable biomarkers and also do the needful questionnaire before and after the intervention.Each patient will dissolve 50 gramme of ordinary dessert or 50 gramme of fortified dessert daily for eight weeks. patients and investigator are blind.

Participants/Inclusion and exclusion criteria

patients who are on dialysis more than 6 months, patients with KT/V > 1.2, patients who are vigilant and can-do and Who are on special regiment for dialysis patients and patients who did not have any changes in their recieved erythropoitin for a month can joined the study and the patients with diabetes, cancer, malignity and autoimmune diseases, who are sensitive to dairy products, who are grafted and still grafted kidney is in their body and patients with vitamin D level more than 70 will not remain in the study.

Intervention groups

Control group: 50 gramme of ordinary dessert daily for 8 weeks in addition to conventional medical treatment of hemodialysis patients Intervention group: 50 gramme of fortified dessert daily for 8 weeks in addition to conventional medical treatment of hemodialysis patients

Main outcome variables

Evaluation of nutritional indices, inflammation, oxidative stress, markers and liver enzyme, state of malnutrition and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100223003408N5**
Registration date: **2019-04-06, 1398/01/17**
Registration timing: **retrospective**

Last update: **2019-04-06, 1398/01/17**
Update count: **0**

Registration date

2019-04-06, 1398/01/17

Registrant information

Name

Maryam Ekramzadeh

Name of organization / entity

Shiraz University of Medical Sciences, Nutrition Department

Country

Iran (Islamic Republic of)

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+98 917 317 3891

Email address

ekramzadeh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

2018-09-23, 1397/07/01

Actual recruitment end date

2019-01-20, 1397/10/30

Trial completion date

2019-06-20, 1398/03/30

Scientific title

Effect of Synbiotic Dessert Fortified with Vitamin D and Calcium on Nutritional Indices, Inflammation, Oxidative stress, Malnutrition and Quality of Life in Hemodialysis Patients

Public title

Synbiotic Dessert Fortified with Vitamin D and Calcium in Hemodialysis Patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are on dialysis more than 6 months Patients with KT/V > 1.2 Patients who are vigilant and can-do Who are on special regiment for dialysis patients Patients who did not have any changes in their recieved erythropoitin for a month

Exclusion criteria:

Patients with diabetes, cancer, malignity and autoimmune diseases Patients who are sensitive to dairy products Patients who are grafted and grafted kidney is in their body Patients with vitamin D level more than 70

Age

From **20 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **42**

Actual sample size reached: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization, Individual, Random allocation software, 11 randomization sequence in permuted blocks of size 4 In this study, the allocation of people to the two groups was done using permutational block method. In this method, T represents the person who receives the intervention, and C represents the person who is in the control group. Considering the quadruple block; we achieved TTCC , TCCT , CTTC , TCCT , CCTT , TCCT , TCTC , TCCT , CCTT , TCTC and TTCC . Then, using the randomization software and sealed envelopes we allocate each one to a patient respectively.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blind: Participants and the researcher responsible for gathering data are blind in this study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

معاونت پژوهشي دانشگاه علوم پزشكي شيراز

Street address

شيراز - خيابان زند - ساختمان مركزي دانشگاه علوم پزشكي شيراز

City

شيراز

Province

Fars

Postal code

71348-14336

Approval date

2018-08-15, 1397/05/24

Ethics committee reference number

IR.SUMS.REC.1397.327

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5, End stage kidney disease: on dialysis

Primary outcomes

1

Description

Malondialdehyde (MDA)

Timepoint

Before and 60 days after intervention

Method of measurement

Spectrophotometry

Secondary outcomes

1

Description

Malnutrition-inflammation score

Timepoint
Before and 60 days after intervention
Method of measurement
Questionnaire

2

Description
Subjective global assessment
Timepoint
Before and 60 days after intervention
Method of measurement
Questionnaire

3

Description
Quality of life
Timepoint
Before and 60 days after intervention
Method of measurement
Questionnaire

4

Description
Vitamin D
Timepoint
Before and 60 days after intervention
Method of measurement
ELISA

5

Description
Total antioxidant capacity
Timepoint
Before and 60 days after intervention
Method of measurement
ELISA

6

Description
hsCRP
Timepoint
Before and 60 days after intervention
Method of measurement
ELISA

7

Description
CBC
Timepoint
Before and 60 days after intervention
Method of measurement
Cell counter

8

Description
Sodium
Timepoint
Before and 60 days after intervention
Method of measurement
Autoanalyser

9

Description
Potasium
Timepoint
Before and 60 days after intervention
Method of measurement
Autoanalyser

10

Description
Phosphor
Timepoint
Before and 60 days after intervention
Method of measurement
Autoanalyser

11

Description
Calcium
Timepoint
Before and 60 days after intervention
Method of measurement
Autoanalyser

12

Description
Albumin
Timepoint
Before and 60 days after intervention
Method of measurement
Autoanalyser

13

Description
Cratinine
Timepoint
Before and 60 days after intervention
Method of measurement
Autoanalyser

14

Description
Urea
Timepoint
Before and 60 days after intervention
Method of measurement
Autoanalyser

15

Description
Ferritin
Timepoint
Before and 60 days after intervention

Method of measurement
ELISA

Intervention groups

1

Description
Intervention group: 50 gramme of fortified dessert per day for 2 months
Category
Treatment - Other

2

Description
Control group: 50 gramme of placebo dessert for 2 months
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid faghihi hospital of Shiraz
Full name of responsible person
Maryam Ekramzade
Street address
Zand street
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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
Shiraz University of Medical Sciences
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Maryam Ekramzade
Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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