Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

The effect of zinc supplementation on appetite status, biochemical parameters and food intake in patients with chronic renal failure under hemodialysis

Protocol summary

Study aim
Determining the effect of zinc supplementation on appetite status and biochemical parameters and food intake in patients with chronic renal failure under hemodialysis

Design
this randomized single-blind clinical trial that will be performed in patients with renal failure under hemodialysis. And will last for 8 weeks. Sampling: Conventional sampling method is used. The sample size is 34 people.

Settings and conduct
Due to the ineffectiveness of the control and intervention group, we will use dialysis unit in Golestan and Razi hospitals of Ahwaz. Patients in a hospital as an intervention group and other hospital patients will be considered as a control group.

Participants/Inclusion and exclusion criteria
inclusion criteria: Age between 20-80 years At least 6 months of dialysis 2-3 times the dialysis per week Not having trouble eating or digestion Non-use of any multivitamin and minerals (except venofer, aprex) Lack of hospitalization or hospitalization during the exclusion criteria: Unwillingness to cooperate

Intervention groups
The intervention group will receive zinc sulfate supplements to improve weigh gain and appetite status and the control group will also receive a placebo.

Main outcome variables
Weight; blood urea nitrogen; creatinine; calcium; phosphorus; potassium; sodium; systolic and diastolic blood pressure; dietary intake

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180621040177N1**
Registration date: **2018-11-19, 1397/08/28**
Registration timing: **retrospective**

Last update: **2018-11-19, 1397/08/28**
Update count: **0**

Registration date
2018-11-19, 1397/08/28

Registrant information

Name
Seyyedeh Maryam Sadeghi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3333 7607

Email address
sadeghi_sm@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-11-14, 1395/08/24

Expected recruitment end date
2017-02-07, 1395/11/19

Actual recruitment start date
2016-11-14, 1395/08/24

Actual recruitment end date
2017-02-27, 1395/12/09

Trial completion date
2017-02-27, 1395/12/09

Scientific title
The effect of zinc supplementation on appetite status, biochemical parameters and food intake in patients with

chronic renal failure under hemodialysis

Public title
Effect of zinc supplementation in patients undergoing hemodialysis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20-80 years At least 6 months of hemodialysis 2-3 with hemodialysis per week No problems in eating and indigestion Non-use of any multivitamin and minerals Lack of hospitalization or hospitalization during the study Lack of infection, liver failure, cancer, thyroid problem when entering or during study
Exclusion criteria:
Unwilling to participate in the study
Age
From **20 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **38**
Actual sample size reached: **38**
Randomization (investigator's opinion)
Randomized
Randomization description
Written on a sheet of paper from 1 to 34 and randomly divided into 2 parts.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants and some health care personnel
Placebo
Used
Assignment
Other
Other design features
This study has two groups of control and intervention. The intervention group received zinc supplements and the control group received a placebo.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
School Of Nutrition And Food Sciences, Razi Blvd, Shiraz
City
shiraz
Province
Fars
Postal code
7153675541
Approval date
2016-11-05, 1395/08/15
Ethics committee reference number
IR.SUMS.REC.1395.143

Health conditions studied

1

Description of health condition studied
Patients with chronic renal failure under hemodialysis
ICD-10 code
N18
ICD-10 code description
Chronic kidney disease (CKD)

Primary outcomes

1

Description
Dry weight
Timepoint
At the beginning of the study and 60 days after taking zinc supplement or placebo
Method of measurement
seca scales

2

Description
Blood urea nitrogen
Timepoint
At the beginning of the study and 60 days after taking zinc supplement or placebo
Method of measurement
autoanalyzer, enzymatic assay

3

Description
Creatinine
Timepoint
At the beginning of the study and 60 days after taking zinc supplement or placebo
Method of measurement
autoanalyzer, enzymatic assay

4

Description
Calcium
Timepoint
At the beginning of the study and 60 days after taking

zinc supplement or placebo

Method of measurement

autoanalyzer

5

Description

phosphorus

Timepoint

At the beginning of the study and 60 days after taking zinc supplement or placebo

Method of measurement

autoanalyzer

6

Description

potassium

Timepoint

At the beginning of the study and 60 days after taking zinc supplement or placebo

Method of measurement

autoanalyzer

7

Description

sodium

Timepoint

At the beginning of the study and 60 days after taking zinc supplement or placebo

Method of measurement

autoanalyzer

8

Description

blood pressure

Timepoint

At the beginning of the study and 60 days after taking zinc supplement or placebo

Method of measurement

Gauge pressure gauge

9

Description

food intake

Timepoint

At the beginning of the study and 60 days after taking zinc supplement or placebo

Method of measurement

2-day 24-h diet recall

Secondary outcomes

1

Description

Appetite Status

Timepoint

At the beginning of the study and 60 days after taking zinc supplement or placebo

Method of measurement

2-day 24-h diet recall

Intervention groups

1

Description

Intervention group: one capsule containing 220 mg zinc sulfate with 50 mg elemental zinc per day, for 60 days, prepared by Al Hawi Tehran Pharmaceutical Company

Category

Treatment - Drugs

2

Description

Control group: one capsule containing cornstarch per day, for 60 days, prepared by Shiraz University of Pharmacy

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Rezaee Eisa

Street address

Khuzestan Province, Ahvaz, Farvardin Blv

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Phone

+98 61 3374 3001

Fax

Email

Golestanjpspital@yahoo.com

Web page address

2

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Rezaee Eisa

Street address

Khuzestan Province, Ahvaz, Amaniye, Felestin St, Facing the governorate

City

Ahvaz

Province

Khouzestan

Postal code

۶۱۹۶۵۱۴۹۴۱

Phone
+98 61 3333 5935

Fax
+98 61 3333 6513

Email
razi-hos@ajums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Akhlaghi Masoumeh

Street address
School Of Nutrition And Food Sciences, Razi Blvd, Shiraz

City
Shiraz

Province
Fars

Postal code
7153675541

Phone
+98 71 3725 1001

Fax
+98 71 3725 7288

Email
msm.akhlaghi@gmail.com

Web page address

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

Full name of responsible person
Masoumeh Akhlaghi

Position
assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
School Of Nutrition And Food Sciences, Razi Blvd, Shiraz

City
Shiraz

Province
Fars

Postal code
7153675541

Phone
+98 71 3725 1001

Email
msm.akhlaghi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Masoumeh Akhlaghi

Position
assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
School Of Nutrition And Food Sciences, Razi Blvd, Shiraz

City
Shiraz

Province
Fars

Postal code
7153675541

Phone
+98 71 3725 1001

Email
msm.akhlaghi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Seyedeh Maryam Sadeghi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

Street address
School Of Nutrition And Food Sciences, Razi Blvd, Shiraz

City
Shiraz
Province
Fars
Postal code
7153675541
Phone
+98 71 3725 1001
Email
sadeghi2306@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
We will publish the data in the form of the article
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available