

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)

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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

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Web page address

2

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Rezaee Eisa

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Akhlaghi Masoumeh

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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

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Name of organization / entity

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Full name of responsible person

Masoumeh Akhlaghi

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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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

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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