

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Evaluation of the effect of zinc supplement on body composition, hand grip strength, appetite and skin lesions in hemodialysis patients

Protocol summary

Study aim

Determination and comparison of appetite, skin disorders and body composition in the intervention and control groups before and after the intervention

Design

Clinical trial with control group, with parallel group, double-blind, randomized, Single phase on 80 patients . For randomization we use SPSS software version 25

Settings and conduct

80 hemodialysis patients referred to the dialysis center of Isfahan Khorshid Hospital will be divided into two groups of 40 people. The studied variables will be measured in all individuals, then for twelve weeks one group with zinc gluconate supplement and the other group with placebo in two They will be complementary and after the complementary period, the variables will be measured and checked again.

Participants/Inclusion and exclusion criteria

Patients who have been on dialysis for at least 3 months, Dialyze at least twice a week, Do not smoke No pregnancy and lactation Lack of nutrition through antral and parenteral No other diseases such as cancer, inflammatory diseases and advanced liver disease Do not take calcium and vitamin D supplements Do not take drugs that affect dependent variables

Intervention groups

Eligible written consent will be obtained from eligible individuals who wish to participate in the study. Individuals are also asked to complete a questionnaire on demographic information, medical history, and medications. Then, using SPSS software and based on the code assigned to each person, by stratified randomization by BMI (between 25-25 and 25-30) and gender are divided into two groups of intervention and control.

Main outcome variables

Zinc gluconate supplementation, appetite changes, skin lesions, body composition, serum zinc level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130903014551N7**

Registration date: **2020-10-05, 1399/07/14**

Registration timing: **prospective**

Last update: **2020-10-05, 1399/07/14**

Update count: **0**

Registration date

2020-10-05, 1399/07/14

Registrant information

Name

Mohammad Hossein Rouhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3183

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s_m_rouhani2003@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of zinc supplement on body composition, hand grip strength, appetite and skin lesions in hemodialysis patients

Public title

The effect of zinc supplementation in hemodialysis patients

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have been on dialysis for at least 3 months
Dialysis at least twice a week
Do not smoke
No pregnancy and lactation
Other diseases such as cancer, inflammatory diseases and advanced liver disease
Do not take calcium and vitamin D supplements
Do not take drugs that affect dependent variables

Exclusion criteria:

Performing a kidney transplant by a person
Enteral and Parenteral Feeding
Individual non-compliance with the study protocol
Show complications side effects by the person to supplement
Change the type of dialysis

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done through block randomization method (permuted blocked randomization). depending on the sample size, each block includes 4 characters and will be used AABB combination. In the following, all possible modes from the combination will be listed and a code will be allocated to each patient. This will be done using a random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

For double blinding of this study, at the beginning, cans contained zinc supplement and placebo were coded as A and B by person other than researcher to ensure researcher and participants were not informed about types of supplement received by participants

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Esfahan University of Medical Sciences, Hezar Jerib street, Esfahan, Iran

City

esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-10-03, 1399/07/12

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.405

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

Z99.2

ICD-10 code description

Dependence on renal dialysis

Primary outcomes

1

Description

appetite

Timepoint

Before and after intervention

Method of measurement

Based on a questionnaire approved by VAS method

2

Description

Skin lesions

Timepoint

Before and after intervention

Method of measurement

Through observation and questionnaire completed by the individual

3

Description

Body composition

Timepoint

Before and after intervention

Method of measurement

By body analysis device and BIA method

4

Description

The power of the grip of the hand

Timepoint

Before and after intervention

Method of measurement

By handgrip device

Secondary outcomes

1

Description

Serum zinc level

Timepoint

Before and after the intervention

Method of measurement

By measuring the amount of zinc in a person's blood

Intervention groups

1

Description

Intervention group: People in this group receive Dine Company Zinc Gluconate 30 mg supplement every day for 12 weeks.

Category

Treatment - Other

2

Description

Control group: People in this group receive a placebo containing lactose and made by the company every day for 12 weeks

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorshid Hospital

Full name of responsible person

Dr. Shahrzad Shahidi

Street address

Ostandari Street - Next to Shahid Dastgheib Boulevard - Khorshid Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

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?

No

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Tavassoli

Position

Executor of plan

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr. Seyed Mohammad Hossein Rouhani

Position

Assistant Professor

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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