

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

City

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Province

Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoo Javanmard

Street address

Deputy of Research & Technology of Esfahan
University of Medical Sciences, Hezar Jarib Street

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Web page address

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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

Name of organization / entity

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Full name of responsible person

Dr. Seyed Mohammad Hossein Rouhani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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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