

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of zinc supplementation on life quality, sleep quality and malnutrition indicators in hemodialysis patients

Protocol summary

Study aim

Evaluation of the effect of zinc supplement on quality of life, quality of sleep and malnutrition indicators

Design

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

Settings and conduct

Eighty hemodialysis patients referred to the dialysis center of Isfahan Khorshid Hospital will be allocated into two groups (n=40 in each group). Subjects in intervention group receive zinc gluconate supplement and subject in control group receive placebo for 12 weeks.

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

Present study contains two groups. Subjects in intervention group receive 30 mg/d of zinc gluconate. A placebo similar to zinc gluconate supplement is administer to control group. placebo contains starch.

Main outcome variables

life Quality, sleep Quality and Malnutrition indicators changes, serum zinc level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130903014551N10**

Registration date: **2020-10-19, 1399/07/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-19, 1399/07/28**

Update count: **0**

Registration date

2020-10-19, 1399/07/28

Registrant information

Name

Mohammad Hossein Rouhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3183

Email address

s_m_rouhani2003@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

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

The effect of zinc supplementation on life quality, sleep quality and malnutrition indicators 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
 Other diseases such as cancer, inflammatory diseases and advanced liver disease

Exclusion criteria:
 consumption of calcium and vitamin D supplements
 Enteral and Parenteral Feeding
 smoking pregnancy and lactation
 consumption of drugs that affect dependent variables

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
 Using SPSS software and based on the code assigned to each person, by stratified randomization based on BMI (between 25-25 and 25-30) and gender, subjects are assigned in the intervention and control groups
 Placed

Blinding (investigator's opinion)
 Double blinded

Blinding description
 Bottles contained zinc supplements and placebos were coded as A and B by person other than researcher to ensure researcher and participants are not aware 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.1399.407

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

sleep quality

Timepoint

quality of sleep assessment Before and immediately after intervention

Method of measurement

pittsburgh questionnaire completed by the individual

2

Description

life quality

Timepoint

quality of life assessment Before and immediately after intervention

Method of measurement

quality of life (HRQOL) questionnaire completed by the individual

3

Description

malnutrition indicators(Albumin,Prealbumin,hs-crp)

Timepoint

Before and immediately after intervention

Method of measurement

blood sample and Auto analyzer

Secondary outcomes

1

Description

Serum zinc level

Timepoint

Before and immediately after the intervention

Method of measurement

atomic absorption

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

khoshid Hospital

Full name of responsible person

Dr. Shahrzad shahidi

Street address

Governorate Street - Next to Shahid Dastgheib Boulevard - Khorshid Hospital

City

esfahan

Province

Isfahan

Postal code

8145833117

Phone

+98 31 3222 2127

Fax

+98 31 3222 2255

Email

nour@mui.ac.ir

Web page address

<http://nour.mui.ac.ir/>

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
Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8138

Fax

+98 31 3668 7898

Email

sh_haghjoo@med.mui.ac.ir

Web page address

<http://research.mui.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

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

sajad hadadian khouzani

Position

Executor of plan

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Esfahan University of Medical Sciences, Hezar Jarib Street, Esfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3183

Fax

+98 31 3792 3183

Email

sajad.haddadiyan@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Seyed Mohammad Hossein Rouhani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Isfahan University of Medical Sciences, Hezar Jarib Street, Azadi Square

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3183

Email

sm_rouhani@nutr.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

sajad hadadian khouzani

Position

supervisor of the study

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Isfahan University of Medical Sciences, Hezar Jarib Street, Azadi Square

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3183

Email

sajad.haddadiyan@gmail.com

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