Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the Effect of Zinc Prescription on Hemoglobin Level and Erythropoetin Dose Requirement in Hemodialysis Patients in comparison with Placebo

Protocol summary

Study aim

Determining the effect of zinc supplement on hemoglobin level in hemodialysis patients before, 3 and 6 months after beginning of the study in 2 groups of intervention and placebo.

Design

Randomized double blind, parallel group, controlled clinical trial, design of 30 patients, randomization is done by permuted block randomization of blocks size 4.

Settings and conduct

In this randomized double blind parallel groups design Hemodialysis patients who attended in Al- Zahra and Khorshid hospitals who fulfill the inclusion criteria will be invited and among them 30 who agree to participate in our study are selected and randomly divided into 2 groups (intervention and control). Intervention group receive zinc tablet and control group receive placebo. Hemoglobin level, serum zinc level and erythropoetin dose are checked before the study, 3 months and 6 months after the beginning of the study. Patient, investigator and health care workers are blinded. Drug and placebo are prepared in similar boxes while differentiated by labels A and B, by a person outside the study.

Participants/Inclusion and exclusion criteria

1- Hemodialysis patients 2- Hemoglobin level less than 12 g/dl 3- Ongoing therapy with injected erythropoetin 4- Consensus on participation in the study 5- Non pregnant and breastfeeding 6- Not having malignancy, inflammatory and severe hepatic diseases

Intervention groups

Patients randomly divided into two groups: 1- DRUG 2- PLACEBO. In DRUG group patients receive one tablet of 30 mg zinc daily for 6 months and in PLACEBO group patients receive one tablet of placebo daily for 6 months also. Serum zinc level will be measured before, 3 months and 6 months after receiving zinc or placebo in both groups.

Main outcome variables

Hemoglobin level,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200827048539N1**
Registration date: **2020-10-19, 1399/07/28**
Registration timing: **prospective**

Last update: **2020-10-19, 1399/07/28**
Update count: **0**

Registration date

2020-10-19, 1399/07/28

Registrant information

Name

Shiva Seirafian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3822 7000

Email address

seirafian@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effect of Zinc Prescription on Hemoglobin Level and Erythropoetin Dose Requirement in Hemodialysis Patients in comparison with Placebo

Public title
The Effect of Zinc on Hemoglobin in Hemodialysis Patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who have been on hemodialysis for at least 3 months More than 18 years of age Consensus on participation in the study Hemoglobin level less than 12 g/dl Patients who are under ongoing therapy with injected erythropoetin Not taking cholrthalidone, tetracycline and penicillin Non pregnant and breastfeeding On hemodialysis for at least twice a week Not having cancer, acute inflammatory disease and severe hepatic failure
Exclusion criteria:
Patients wanting to discontinue the cooperation for any reason Discontinuing hemodialysis therapy Surgical operation during the study Blood transfusion during the study Hemorrhage during the study Development of malignant tumors during the study Pregnancy during the study Intolerance of drug Non-compliance with the intervention (less than 70%)
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation in current study will be done using permuted block randomization of block size 4, and each patient is as a unit of randomization, and random sequence generation will be done using statistical software and will be conducted using sealed envelops.
Blinding (investigator's opinion)
Double blinded
Blinding description
All the patients, investigators, health care workers and drug prescribers will be blinded. Drug and placebo will be prepared in simple and similar boxes by a trained person who is not in the study, does not work in the dialysis ward and does not have any relations with any of the people in the study group or health care workers. Drug and placebo are marked by labels A and B in similar boxes. Then they are shared by health care workers who have no contact with the divider of the drug. This drug A and B are randomly distributed among patients who have been sampled randomly. The test results and other data are gathered by the investigators. Only data analyzer is informed about drug A and B.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
Secondary trial Id
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Vice-Chancellery for Research and Technology, Isfahan University of Medical Sciences, Hezar Jerib Street,
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-08-25, 1399/06/04
Ethics committee reference number
IR.MUI.MED.REC.1399.432

Health conditions studied

1

Description of health condition studied
End stage renal disease on hemodialysis
ICD-10 code
Z99.2
ICD-10 code description
Dependence on renal dialysis

2

Description of health condition studied
Anemia

ICD-10 code
N18.6
ICD-10 code description
End stage renal disease

Primary outcomes

1

Description
Blood hemoglobin level
Timepoint
Before, 3 and 6 months after the intervention
Method of measurement
Hemoglobin measurement by automated hematology analyzer, sysmex-21N, Japan

Secondary outcomes

1

Description
The amount of prescribed erythropoetin
Timepoint
Before, 3 and 6 months after the intervention
Method of measurement
By observation and questionnaire

2

Description
Serum zinc level
Timepoint
Before, 3 and 6 months after the intervention
Method of measurement
Laboratory AUDIT kit (Delta Darman Part, Tehran, Iran), measured by OLYMPUS 2700 autoanalyzer, Japan

Intervention groups

1

Description
Intervention group: 30 hemodialysis patients enroll in the study using 30 mg zinc gluconate tablets containing 30 mg elemental zinc (Dineh pharmaceutical Co., Tehran, Iran). The patients are taught to take one tablet with water after breakfast; and on dialysis days, after the meal post dialysis session; daily for 6 months. The drug will be offered in hemodialysis ward weekly and to make sure the drug is taken by the patients, they are asked to return the empty box.
Category
Treatment - Drugs

2

Description
Control group: 30 hemodialysis patients enroll in the study and will receive the placebo with the same size, smell, color and packaging produced by Isfahan Faculty of Pharmacy. The patients are taught to take the placebo with water daily after breakfast, and on dialysis days after the meal post dialysis session; for 6 months. The patients will receive the placebo in hemodialysis wards weekly and to make sure the drug is taken by the patients, they are asked to return the empty box.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Shiva Seirafian
Street address
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2

Recruitment center
Name of recruitment center
Noor-Aliasghar hospital
Full name of responsible person
Elham Kabiri Naeini
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh haghjooy Javanmard
Street address
Vice-Chancellor for Research and Technology, No. 4 Bluid., Isfahan University of Medical Sciences, Hezar

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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
Shiva Seirafian

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Adult Nephrology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Associate professor

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Person responsible for updating data

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Elham Kabiri Naeini

Position
Nephrology fellow

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Specialist

Other areas of specialty/work
Internal Medicine

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kabirielham20@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

1- Primary outcome including hemoglobin level in two groups of intervention 2- Secondary outcome including erythropoetin dose changes in two groups of intervention

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Academic persons only can apply to receive it.

Under which criteria data/document could be used

1- Compare with or add to similar data of other studies 2- Doing statistical analysis other than we did provided that the right of first investigators be preserved.

From where data/document is obtainable

By e-mail: seirafian@med.mui.ac.ir

What processes are involved for a request to access data/document

One month after receiving inquiry, email and mobile number, it will be responsed.

Comments