

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 Erythropoietin 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 erythropoietin
Not taking cholethralidone, 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 envelopes.

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,

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Province

Isfahan

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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

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2**Recruitment center****Name of recruitment center**

Noor-Aliasghar hospital

Full name of responsible person

Elham Kabiri Naeini

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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?

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 updating data

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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 erythropoietin 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 responded.

Comments