Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the Effect of Zinc supplement on CRP and NLR inflammatory factor in MHD patients

Protocol summary

Study aim

The effect of zinc supplementation on inflammatory factor CRP and NLR in patients with renal failure undergoing hemodialysis Measurement of serum zinc levels in hemodialysis patients Measurement of serum CRP levels in hemodialysis patients Measurement of NLR in hemodialysis patients using KDQOL-SF1.3 (Kidney Disease Quality of Life Short Form)questionnaire

Design

The study is a double-blind prospective randomized clinical trial in crossover form. The number of 40 patients (48 patients including 20% dropout) are randomly divided into two groups of 24 cases.

Settings and conduct

Before the start of the first dose of the drug, blood samples are taken from the patients, and the level of serum zinc and the quality of life are recorded by KDQOL-SF 1.3 questionnaire and other investigated factors. After 30 days and at the end of the study (60 days), all aspects will be measured and compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-People over 18 years old 2-Zinc level less than 70 mcg / dL 3-Has been on regular hemodialysis for at least six months 4-Undergo hemodialysis at least twice a week. Exclusion criteria: 1-Patient dissatisfaction 2-The patient hospitalized for the last three months 3-Use of zinc supplement during the previous two weeks (use of specific multivitamins for dialysis patients is not concluded) 4-Use of selenium supplement in the last two weeks

Intervention groups

After obtaining informed consent from the patients, the first group will be given 50 mg of zinc (one tablet) daily for 30 days, and the second group will receive a placebo tablet. After 30 days, the first group will be given the placebo, and the second group will be assigned 50mg of zinc (one tablet) daily for 30 days.

Main outcome variables

CRP,NLR(neutrophil lymphocyte ratio)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160412027346N8**
Registration date: **2022-08-02, 1401/05/11**
Registration timing: **prospective**

Last update: **2022-08-02, 1401/05/11**
Update count: **0**

Registration date

2022-08-02, 1401/05/11

Registrant information

Name

Shadi Ziaie

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8887 3704

Email address

shadiziaie@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-27, 1401/06/05

Expected recruitment end date

2022-10-27, 1401/08/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluating the Effect of Zinc supplement on CRP and NLR inflammatory factor in MHD patients

Public title
Evaluating the Effect of Zinc supplement on CRP and NLR inflammatory factor in MHD patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People over 18 years old Zinc level less than 70 mcg/ dL Has been on regular hemodialysis for at least 6 month Undergo hemodialysis at least twice a week

Exclusion criteria:
Patient dissatisfaction Have been hospitalized for the last 3 months Use of zinc supplement in the last two weeks (use of specific multivitamins for dialysis patients is not recommended) Use of selenium supplement in the last two weeks

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The drug and placebo were precisely identical in shape and appearance and prepared in similar packaging. A specific code was assigned to the placebo and a code to the drug. Furthermore, it is presented to the patients according to the randomization table. Only the principal investigator will know the code of the drugs. Medicines are given to patients by ward nurses who do not know the code of medicines.

Blinding (investigator's opinion)
Double blinded

Blinding description
The drug and the placebo are in a package with a standard label and the same amount, and each box is assigned a code that is only available to the researcher, depending on whether it is a drug or a placebo.

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethics committee of Shahid Beheshti University of Medical Sciences

Street address
Tehran Province, Tehran, Velenjak, Arabi Ave

City
Tehran

Province
Tehran

Postal code
19839-63113

Approval date
2022-03-09, 1400/12/18

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1401.004

Health conditions studied

1

Description of health condition studied
End stage kidney disease under hemodialysis

ICD-10 code
N18.6

ICD-10 code description
End stage renal disease

Primary outcomes

1

Description
The effect of zinc supplementation on CRP

Timepoint
The beginning of the study, 30 and 60 days

Method of measurement
Laboratory test

Secondary outcomes

1

Description
The effect of zinc supplementation on NLR (nutrophil,lymphocyte ratio)

Timepoint
The beginning of the study, day 30 and 60

Method of measurement
laboratory test

Intervention groups

1

Description
Intervention group: Administration of 50 mg zinc sulfate

tablets - once a day - orally - for one month - manufactured by Alhawi company

Category

Treatment - Drugs

2

Description

Control group: Administration of placebo - once a day - orally

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Labbafinejad Medical center

Full name of responsible person

Dr Shadi Ziaie

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shayan Mastoor Tehrani

Position

Clinical pharmacy resident

Latest degree

Medical doctor

Other areas of specialty/work

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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
Yes - There is a plan to make this available
Title and more details about the data/document
At the end of the study of all patient data, after making them non-identifiable and performing the statistical analysis mentioned in the work method, necessary reports will be extracted and a part of it related to the main outcome will be shared.
When the data will become available and for how long
6 months after publishing the results
To whom data/document is available
responsible investigator, Physicians, academician investigators
Under which criteria data/document could be used
only with permission of responsible investigator or regulatories
From where data/document is obtainable
Responsible investigator
What processes are involved for a request to access data/document
Through contacting with responsible investigator
Comments