

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The effect of oral zinc on nutritional and inflammatory factors in chronic hemodialysis patients

Protocol summary

Study aim

Evaluation of The effect of oral zinc on nutritional and inflammatory factors in chronic hemodialysis patients in Boali hospital

Design

randomized clinical trial with control group.single blind

Settings and conduct

The trial was conducted at Boo Ali Hospital in Tehran and randomly divided into two groups of intervention and control.

Participants/Inclusion and exclusion criteria

inclusion criteria:hemodialysis patients consent to participate in study Exclusion criteria:Patients receiving tetracycline and quinolone.

Intervention groups

The intervention group consisted of patients who received two capsules of 110 mg zinc sulfate daily along with their other medications for 3 months. The control group consisted of patients who received 2 capsules of 110 mg zinc sulfate daily along with their other medications for 3 months.

Main outcome variables

Hba1c, predialysis
BUN, albumin, hemoglobin, TG, ESR, ferritin, crp

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150706023084N5**
Registration date: **2020-04-06, 1399/01/18**
Registration timing: **retrospective**

Last update: **2020-04-06, 1399/01/18**

Update count: **0**

Registration date

2020-04-06, 1399/01/18

Registrant information

Name

MARYAM SHIEHMORTEZA

Name of organization / entity

AZAD UNIVERSITY PHARMACEUTICAL SCIENCES

Country

Iran (Islamic Republic of)

Phone

+98 212640056

Email address

shiehmorteza@iaups.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-21, 1398/02/31

Expected recruitment end date

2019-08-22, 1398/05/31

Actual recruitment start date

2019-05-21, 1398/02/31

Actual recruitment end date

2019-08-22, 1398/05/31

Trial completion date

2019-08-22, 1398/05/31

Scientific title

The effect of oral zinc on nutritional and inflammatory factors in chronic hemodialysis patients

Public title

Evaluation of the effect of oral zinc in patients with chronic hemodialysis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Hemodialysis patients consenting to participate in the study

Exclusion criteria:

Patients receiving tetracycline and quinolone.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **2**

Patient serum sample

Actual sample size reached: **80**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Patient serum sample

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Method: Simple randomization

Randomization tool: Random Number Table

Blinding (investigator's opinion)

Single blinded

Blinding description

All patients who were included in the study were randomly assigned to either drug or placebo groups by random number table. Patients were unaware of the drug or placebo intervention. But the researcher and the doctor were aware of the drug or placebo. Patients and medications were coded by the researcher. The blinding was such that the placebo was the same color and flavor as the drug. That is, the drug and the placebo were both similar in appearance. But the placebo capsules contained cornstarch.

Placebo

Used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Department of Pharmaceutical Sciences, Tehran Islamic Azad University of Medical

Street address

Dr Shariati Ave., Gholhak, Yakhchal Ave., Islamic Azad University of Pharmaceutical Sciences Branch

City

Tehran

Province

Tehran

Postal code

193956466

Approval date

2019-01-05, 1397/10/15

Ethics committee reference number

IR.IAU.PS.REC.1397.324

Health conditions studied**1****Description of health condition studied**

Inflammation and malnutrition in patients with chronic hemodialysis

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

HBA1C

Timepoint

Before the start of the study and three months after taking oral zinc tablets

Method of measurement

Variable serum levels were measured by chromatography

2**Description**

Albumin

Timepoint

Before the start of the study and three months after taking oral zinc tablets

Method of measurement

The serum levels of the variable were measured by Bromocresol Green.

3**Description**

BUN or blood urea nitrogen

Timepoint

Before the start of the study and three months after taking oral zinc tablets

Method of measurement

Serum levels of variable blood were measured by tacophoresis.

4**Description**

Hemoglobin

Timepoint

Before the start of the study and three months after taking oral zinc tablets

Method of measurement

Serum levels of variable blood were measured by cyanometho hemoglobin.

5

Description

Triglycerides

Timepoint

Before the start of the study and three months after taking oral zinc tablets

Method of measurement

The serum levels of the variable blood were measured by a special kit using triglyceride oxidase.

6

Description

ESR or erythrocyte sedimentation rate

Timepoint

Before the start of the study and three months after taking oral zinc

Method of measurement

The serum level of the variable in question was measured by the Westergreen method.

7

Description

ferritin

Timepoint

Before the start of the study and three months after taking oral zinc

Method of measurement

Serum levels of variable blood were measured by RIA.

8

Description

CRP or C reactive protein

Timepoint

Before the start of the study and three months after taking oral zinc

Method of measurement

Blood serum levels of the variable were measured with special latex agglutination kits.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group received 2 capsules of zinc sulfate 110 mg daily along with their other medications.

Category

Treatment - Drugs

2

Description

Control group: The group received 2 placebo capsules of zinc sulfate 110 mg daily along with their other medications.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali Hospital, Tehran

Full name of responsible person

Dr.farahnaz pasha

Street address

Tehran - Imam Hossein Square - At the beginning of Damavand Street

City

tehran

Province

Tehran

Postal code

17117

Phone

+98 21 3334 8036

Fax

Email

booali.hospital96@gmail.com

Web page address

<http://bouali.iautmu.ac.ir/fa>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr.farshad hashemian

Street address

Tehran. Islamic Azad University of Medical Sciences

City

tehran

Province

Tehran

Postal code

1916893813

Phone

+98 21 2200 6660

Fax

+98 21 2260 0714

Email

info@iau.ac.ir

Web page address

<http://iaups.iautmu.ac.ir/fa>

Grant name

Grant code / Reference number

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

No

Title of funding source

Student herself

Proportion provided by this source

100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
hanieh bahrami tabar
Position
University student
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Kangavar, Taleghani Street, the end of Keshavarzi
Bank Alley
City
kangavar
Province
Kermanshah
Postal code
6741713445
Phone
+98 83 4822 1456
Email
hanieh.bahramitabar@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
maryam shiehmorteza
Position
Doctor of Pharmacotherapy
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Dr Shariati St., Gholak St., Islamic Azad University of
Pharmaceutical Sciences
City
tehran
Province

Tehran
Postal code
1941933111
Phone
+98 21 2264 0051
Email
shiehmorteza@iaups.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
hanieh bahrami tabar
Position
University student
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Kangavar, Taleghani Street, the end of Keshavarzi
Bank Alley
City
kangavar
Province
Kermanshah
Postal code
6741713445
Phone
+98 83 4822 1456
Email
hanieh.bahramitabar@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