

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

The effect of zinc supplementation on blood pressure in dialysis patients

Protocol summary

Study aim

Determining the effect of zinc supplementation on systolic and diastolic blood pressure of dialysis patients

Design

A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 130 patients. Block randomization method with Randomization.com online software was used for randomization.

Settings and conduct

This study will be conducted in the form of a double-blind randomized clinical trial in 1401 at Amirul Mominin Hospital in Arak. In this way, patients with chronic renal failure who are undergoing continuous treatment with hemodialysis will be included in the study after obtaining informed consent. Then the patients will be randomly divided into intervention and control groups. Participating patients, clinical caregivers and researchers will be blinded in this project.

Participants/Inclusion and exclusion criteria

Inclusion criterias: at least 3 months have passed since dialysis, over 18 years old, dialysis at least 2 times a week. Exclusion criterias: pregnancy and breastfeeding, suffering from other chronic diseases, blood transfusion or bleeding during the study

Intervention groups

The patients in the intervention group will receive 40 mg oral zinc supplement (Dana Pharmaceutical Company) twice a day for three months in addition to their main drugs since the beginning of the study. Patients in the control group will also receive an oral placebo capsule similar in size, shape and size to the medication in the intervention group twice a day for three months in addition to their main medications.

Main outcome variables

Systolic blood pressure, diastolic blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230107057068N1**

Registration date: **2023-02-08, 1401/11/19**

Registration timing: **prospective**

Last update: **2023-02-08, 1401/11/19**

Update count: **0**

Registration date

2023-02-08, 1401/11/19

Registrant information

Name

Azadeh Aziminejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3224 9783

Email address

sina_mehra@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-05-21, 1402/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of zinc supplementation on blood pressure in dialysis patients

Public title

The effect of zinc on the blood pressure of dialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

At least 3 months have passed since their dialysis
Dialyses at least 2 times a week Age above 18 years

Exclusion criteria:

Pregnancy and breastfeeding Suffering from other chronic diseases Blood transfusion or bleeding during the study

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

In this method, first, a random sequence is created by one of the mentioned methods, then, based on the sample size of the research, a number of envelopes are prepared with aluminum foil (in order to make the content of the envelopes unclear), and each of the random sequences created is recorded on a card. The cards are placed in the letter envelopes in order. In order to preserve the random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box in order.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patient, researcher, care personnel and drug prescriber will be blinded. The drug and the placebo, which are already prepared and have the same shape, are distinguished from each other by A and B stickers. Then medicine A and B are distributed by health care workers who have no previous contact with the person distributing the medicine between the patients who have been randomly divided into two groups. The results of experiments and data are collected by the researcher. Only the person analyzing the information knows about drug A and B.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Payambar azam complex, Basij Sq., Sardasht Town

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2022-09-11, 1401/06/20

Ethics committee reference number

IR.ARAKMU.REC.1401.196

Health conditions studied

1

Description of health condition studied

Chronic kidney disease

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease (CKD)

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Before starting the study and twice a week for three months

Method of measurement

Using electronic pressure gauge Citizen CH 304 (Japan)

2

Description

Diastolic blood pressure

Timepoint

Before starting the study and twice a week for three months

Method of measurement

Using electronic pressure gauge Citizen CH 304 (Japan)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 65 patients in the intervention group will receive 40 mg oral zinc supplement (Dana Pharmaceutical Company) twice a day for three months in addition to their main drugs since the beginning of the study.

Category

Treatment - Drugs

2

Description

Control group: 65 patients in the control group will also receive oral placebo capsules similar in size, shape and size to the medication in the intervention group twice a day for three months in addition to their main medications.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir-al-momenin hospital

Full name of responsible person

Azadeh Aziminejad

Street address

Payambar azam complex, Basij Sq., Sardasht Town

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3848176941

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it-amiralmomenin@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mahdi Salehi

Street address

Payambar azam complex, Basij Sq., Sardasht Town

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3848176341

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research@arakmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Azadeh Aziminejad

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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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

resident

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Azadeh Aziminejad

Position

resident

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No.18,kosar Aven,farabi Blv,Arak

City

Arak

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