

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Evaluation of the effect of zinc dose received through supplements for kidney diseases patients in Iran (Nephrovit® or Nephrotonic®) on iron stores and anemia in non-dialysis chronic kidney diseases patients

Protocol summary

Study aim

Determining the effect of zinc dose in multivitamin products of CKD patients on the progression of anemia (hemoglobin level) in these patients

Design

clinical trial with a control and intervention group, without blinding, randomized in 60 patients

Settings and conduct

CKD patients referred to the nephrology clinic of Imam Khomeini Hospital in Sari (Mazandaran UMS) will enter the study after obtaining written consent. In one of the two groups receiving nephrovit or nephrotonic (25 mg of zinc) daily or take nephrotonic with a lower dose of zinc (7.5 mg) for 3 months. at the beginning of the study and then three months after the intervention, blood count tests and iron profiles and ceruloplasmin, copper and zinc levels is checked.

Participants/Inclusion and exclusion criteria

Inclusion: Patients aged 18-85 years have stage 3 or more CKD, who have been treated with nephrovit or nephrotonic for more than three months. Exclusion: History of chronic infection or severe infection (sepsis) in the last month or cancer, alcohol abuse or use of anemia-inducing drugs (some antibiotics such as linezolid, chloramphenicol and Isoniazid, antiviral drugs in the treatment of AIDS for the last month- routine use of NSAIDs - chemotherapy drugs, hydroxyurea, azathioprine, 6-mercaptopurin, sulfasalazine, cotrimoxazole and methotrexate), Patients with a history of blood transfusion within 1 month prior to enrollment.

Intervention groups

In the control group, take a daily routine for nephrovit or nephrotonic (25 mg of zinc) In the intervention group, receiving nephrotonic supplement formulation with the same components of the previous formulation but containing 7.5 mg of zinc (or receiving a multivitamin supplement from Nephrovit or Nephrotonic and one day

between B Campelx)

Main outcome variables

Hb, HCT, ferritin, TIBC, MCV, serum iron and plasma levels of zinc, copper and ceruloplasmin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100111003043N15**

Registration date: **2021-08-14, 1400/05/23**

Registration timing: **prospective**

Last update: **2021-08-14, 1400/05/23**

Update count: **0**

Registration date

2021-08-14, 1400/05/23

Registrant information

Name

Simin Dashti-Khavidaki

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

dashtis@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-03-19, 1400/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of zinc dose received through supplements for kidney diseases patients in Iran (Nephrovit® or Nephrotonic®) on iron stores and anemia in non-dialysis chronic kidney diseases patients

Public title

The effect of zinc dose on anemia in non-dialysis chronic kidney diseases patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged 18-85 years, with stage 3 or more CKD according to the KDIGO guideline, who have been treated with nephrovitis or nephrotonics for more than three months, No significant changes in their diet.

Exclusion criteria:

History of chronic infection (AIDS, bacterial, fungal or parasitic infections), severe infection (sepsis) in the last month, cancer, alcohol abuse, use of anemia-inducing drugs (some antibiotics such as linezolid, cotrimoxazole, chloramphenicol and Isoniazid, routine use of nonsteroidal anti-inflammatory drugs, chemotherapy drugs, hydroxyurea, azathioprine, 6-mercaptopurin, sulfasalazine, and methotrexate), treatment with steroids or immunosuppressant, hospitalization, history of blood transfusion within 1 month prior to enrollment.

AgeFrom **18 years** old to **85 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **60**

More than 1 sample in each individual

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

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization between two groups of the study is performed by block randomization method with block size of 4. 6 possible arrangements are possible. Excel-derive, random number generation is used for assigning blocks. 15 blocks are selected.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics committees of the Institute of Pharmaceutical Sciences- Tehran University of Medical

Street address

16 Azar

City

Tehran

Province

Tehran

Postal code

1417614411

Approval date

2021-06-14, 1400/03/24

Ethics committee reference number

IR.TUMS.TIPS.REC.1400.048

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

Patients with chronic kidney disease stage 3 to 5

ICD-10 code

D63.1

ICD-10 code description

Anemia in chronic kidney disease

Primary outcomes**1****Description**

Hemoglobin level

Timepoint

At the beginning of the study and three months after the intervention

Method of measurement

blood test

2**Description**

Hematocrit rate

Timepoint

At the beginning of the study and three months after the intervention

Method of measurement

blood test

3

Description

Ferritin level

Timepoint

At the beginning of the study and three months after the intervention

Method of measurement

blood test

4

Description

The amount of serum iron

Timepoint

At the beginning of the study and three months after the intervention

Method of measurement

blood test

5

Description

Plasma level of copper

Timepoint

At the beginning of the study and three months after the intervention

Method of measurement

blood test

6

Description

Plasma level of zinc

Timepoint

At the beginning of the study and three months after the intervention

Method of measurement

blood test

7

Description

Plasma levels of ceruloplasmin

Timepoint

At the beginning of the study and three months after the intervention

Method of measurement

blood test

8

Description

MCV rate

Timepoint

At the beginning of the study and three months after the intervention

Method of measurement

blood test

9

Description

TIBC rate

Timepoint

At the beginning of the study and three months after the intervention

Method of measurement

blood test

Secondary outcomes

1

Description

mean doses of iron (oral or intravenous)

Timepoint

during 1 month before the study, and during the study period

Method of measurement

Prescribed iron

2

Description

mean doses of erythropoietin

Timepoint

during 1 month before the study, and during the study period

Method of measurement

Prescribed erythropoietin

Intervention groups

1

Description

In the control group, patients receive currently available supplements for kidney patients, (nephrovit or nephrotonic containing 25 mg of zinc) daily. Patients' blood samples are taken at the beginning of the study and at the end of 3 months intervention to assess complete blood counts, iron stores, serum zinc, copper and seruloplasmin concentrations.

Category

Treatment - Drugs

2

Description

In the intervention group, new supplement formulation that will be made by Zahravi company will be administered in daily doses. This new formulation contains the same components as nephrotonic with only difference of consisting 7.5 mg zinc instead of 25mg in current formulation. Patients' blood samples are taken at the beginning of the study and at the end of 3 months intervention to assess complete blood counts, iron stores, serum zinc, copper and seruloplasmin concentrations.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Sari

Full name of responsible person

Simin Dashti-Khavidaki

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Razi Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

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16 Azar St.,

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Nazari Taloki

Position

Clinical Pharmacy resident

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Simin Dashti-Khavidaki

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Zahra Nazari Taloki

Position

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Latest degree

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Other areas of specialty/work

Medical Pharmacy

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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

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

Title and more details about the data/document

The data related to the main outcomes of the study is shared as an SPSS file after deidentifying the individuals.

When the data will become available and for how long

The data will be available three months after the results are published. Data would be available for one year.

To whom data/document is available

The data will be made available to researchers working at academic institutions.

Under which criteria data/document could be used

Individuals or institutions that want to use the data must sign a memorandum of understanding with Tehran University of Medical Sciences.

From where data/document is obtainable

Applicants can contact Dr. Simin Dashti-Khavidaki to receive the data. Phone: 0098-21-66954709 Email: dashtis@tums.ac.ir

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

The applicant's request will be raised in the research session of the Faculty of Pharmacy. After confirmation and signing of the memorandum, the data will be provided to the applicant within about two months.

Comments