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-mercaptoporin, 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)

Phone
+98 21 6695 4709

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-mercaptoporin, sulfasalazine, and methotrexate), treatment with steroids or immunosuppressant, hospitalization, history of blood transfusion within 1 month prior to enrollment.
Age
From **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

Street address
Razi Street

City
Sari

Province
Mazandaran

Postal code
48166-33131

Phone
+98 11 3335 0670

Email
dashtis@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohammad Ali Sahraian

Street address
16 Azar St.,

City
Tehran

Province
Tehran

Postal code
1417614411

Phone
+98 21 6695 4709

Email
dashtis@sina.tums.ac.ir

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

Street address
Enghelab Square, 16 Azar St., FAculty of Pharmacy, Department of Clinical Pharmacy

City
Tehran

Province
Tehran

Postal code
1417614411

Phone
+98 21 6695 4709

Fax
+98 21 6695 4709

Email
zahra.nazari.taloki@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Simin Dashti-Khavidaki

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

Street address
Enghelab Square, 16 Azar St., School of Pharmacy, Department of Clinical Pharmacy

City
Tehran

Province
Tehran

Postal code
1417614411

Phone
+98 21 6695 4709

Fax
+98 21 6695 4709

Email
dashtis@sina.tums.ac.ir

Person responsible for updating data

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
Street address
Enghelab Square, 16 Azar St., School of Pharmacy, Department of Clinical Pharmacy
City
Tehran
Province
Tehran
Postal code
1417614411
Phone
+98 21 6695 4709
Fax
+98 21 6695 4709
Email
zahra.nazari.taloki@gmail.com

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