Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of injectable iron supplementation on FGF23 levels in hemodialysis patients

Protocol summary

Study aim
Determination of the relationship between fgf23 level and serum iron and ferritin level before and after iron supplement injection in hemodialysis patients

Design
Study Type: Clinical Trial (Pre and Post Study) Case study: All hemodialytic patients Sample size: The sample size is estimated to be 45 according to the statistical formula obtained from the same study.

Settings and conduct
Methods: All patients with hemodialysis at the center of dialysis of Ali ibn Abi Taleb Hospitals will enter into the study. The level of 23FGF, serum iron and ferritin, and the transferrin saturation percentage of patients will be assessed and the baseline level will be determined. Then All patients will receive 100 mg of an equal dose of 10 mg each dose of dialysis 10 times in a similar manner. In the end, The above test levels will be re-evaluated.

Participants/Inclusion and exclusion criteria
Inclusion criteria : -All patients who have completed their dialysis for at least 3 months. -All patients aged18 to70years. -All patients have ferritin less than200and transferrin saturation less than20%. Exclusion criteria: -patients dissatisfaction -Malignancy -Parathyroidectomy -Infection -Recent consumption of corticosteroid

Intervention groups
Intervention group: All those who are eligible for the study will be treated with 100 mg of injectable iron (Venofer) with dialysis 10 times for 3 months.

Main outcome variables
Determination of FGF23 levels

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190506043488N1**
Registration date: **2019-12-27, 1398/10/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-27, 1398/10/06**
Update count: **0**

Registration date
2019-12-27, 1398/10/06

Registrant information
Name
Foroogh Asli
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 54 3329 5630
Email address
foroogha66@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
2019-10-23, 1398/08/01

Actual recruitment end date
2020-04-20, 1399/02/01

Trial completion date
2020-09-21, 1399/06/31

Scientific title
The effect of injectable iron supplementation on FGF23 levels in hemodialysis patients

Public title
The effect of intravenous iron on fgf23 and iron profile

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with hemodialysis who have completed their dialysis for at least 3 months. All patients with hemodialysis aged 18 to 70 years. All patients with hemodialysis have ferritin less than 200 and transferin saturation less than 20 %.

Exclusion criteria:

Dissatisfaction patients to enter the study transfusion Malignancy Parathyroidectomy Infection of any type (catheter infection, UTI,....) Recent consumption of corticosteroid Active bleeding Advanced heart disease liver disease

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **45**

Actual sample size reached: **45**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Sistan and Baluchestan Zahedan - Persian Gulf Highway - Imam Khomeini Mosque - Ali Bin Abi Talib Hospital

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Approval date

2019-09-21, 1398/06/30

Ethics committee reference number

IR.ZAUMS.REC.1398.237

Health conditions studied

1

Description of health condition studied

Iron deficiency anemia in hemodialysis patients

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Fibroblast growth factor 23 level

Timepoint

Measurement of Fibroblast growth factor 23 level at the beginning of the study (before intervention) and 3 months after intervention

Method of measurement

Laboratory measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Hemodialysis patients who meet the inclusion criteria will receive 100 mg of intravenous iron (venoffer) supplement 10 times during 3 months after each dialysis.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ibn Abi taleb Hospital

Full name of responsible person

Ali Alidadi

Street address

Ali Bin Abi Talib Hospital ., Persian Gulf Highway ., Zahedan town ., sistan and Baluchestan province

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Dr. Nourmohammad Bakhshani - Deputy of Research and Technology of the University
Street address
Ali Bin Abi Talib Hospital ., Persian Gulf Highway ., Zahedan town ., sistan and Baluchestan province
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Deputy of Research and Technology of Zahedan University of Medical Science
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
Zahedan University of Medical Sciences
Full name of responsible person
Foroogh Asli
Position
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
The whole potential data is unpublished after being unidentifiable
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Only available to scholars working in academic and academic institutions
Under which criteria data/document could be used
Use of study data is permitted for any use by researchers working in academic and scientific institutions
From where data/document is obtainable
Ali ebn Abitalib Hospital, Zahedan, Department of Hemodialysis Deputy of Research of Zahedan University of Medical Sciences, Faculty of Medicine Dr. Ali Alidadi, professor of the thesis, telephone number 09120621590
What processes are involved for a request to access data/document
It takes about 1 month from the request of the applicant to access data files or time documentation
Comments