

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

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

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

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

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

Update count: **0**

Registration date

2019-12-27, 1398/10/06

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.

Registrant information

Name

Foroogh Asli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5630

Email address

foroogha66@gmail.com

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.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria : -All patients who have completed their dialysis for at least 3 months. -All patients aged 18 to 70 years. -All patients have ferritin less than 200 and transferrin saturation less than 20%. Exclusion criteria: - patients dissatisfaction -Malignancy -Parathyroidectomy - Infection -Recent consumption of corticosteroid

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

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

Scientific title

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190506043488N1**

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

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 transferrin 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

City

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Email

Alihos@zaums.ac.ir

Web page address

<https://Alihos.zaums.ac.ir>

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

Internal Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Foroogh Asli

Position

Internal medicine assistant

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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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