

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of the effect of erythropoietin and placebo with the combination of l-carnitine and erythropoietin on anemia in hemodialysis patients

Protocol summary

Study aim

Comparison of the effect of erythropoietin and placebo with the combination of l-carnitine and erythropoietin on anemia in hemodialysis patients

Design

Phase 2-3 randomized clinical trial with parallel groups which will be conducted on 24 patients on hemodialysis

Settings and conduct

This study will be conducted with the aim of comparison of the effect of erythropoietin and placebo with the combination of l-carnitine and erythropoietin on anemia in 24 hemodialysis patients attending Ali Ebne Abitaleb hospital in Zahedan city. After inclusion in the study, the patients will be assigned into two groups; erythropoietin and placebo and erythropoietin plus l-carnitine group. Erythropoietin will be given with a dose of 2000 IU three times a week subcutaneously in both groups and in the erythropoietin plus l-carnitine group, l-carnitine tablet will be given with a dose of 20 mg/kg daily orally and in the erythropoietin and placebo group, in addition to erythropoietin, the patients will receive l-carnitine placebo daily orally. Patients in both groups will be followed up for 3 months and after the treatment, the hemoglobin level will be measured by laboratory in both groups and will be compared together.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age of less than 30 years, having a history of at least 6 month of dialysis Exclusion criterion: having an active infectious or inflammatory disease

Intervention groups

Intervention group 1: receiving erythropoietin 2000 IU three times a week subcutaneously plus l-carnitine placebo daily orally for three months Intervention group 2: receiving erythropoietin 2000 IU three times a week subcutaneously plus l-carnitine tablet 20 mg/kg daily orally

Main outcome variables

Serum hemoglobin level

General information

Reason for update

Editing the title of the clinical trial

Acronym

IRCT registration information

IRCT registration number: **IRCT20200225046620N1**

Registration date: **2020-03-24, 1399/01/05**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-10, 1399/09/20**

Update count: **1**

Registration date

2020-03-24, 1399/01/05

Registrant information

Name

Vahid Sheikhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5715

Email address

dr.sheikhie@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Comparison of the effect of erythropoietin and placebo with the combination of l-carnitine and erythropoietin on anemia in hemodialysis patients

Public title
The effect of l-carnitine and erythropoietin on anemia in hemodialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of less than 30 years Having a history of at least 6 month of dialysis

Exclusion criteria:

Having an active infectious or inflammatory disease

Age

To 30 years old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: 24

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with blocks of 6. The patients will be randomly assigned into 2 groups of 12. Considering the sample size of 24 (12 patients in erythropoietin with group and 12 patients in erythropoietin plus l-carnitine group) , 4 blocks with 6 people will be selected; in each block there will be 3 cards of each group. So by selecting each block, 3 people will be assigned into each group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person evaluating the patients won't be aware of the patients assignment

Placebo

Used

Assignment

Parallel

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

Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9916789547

Approval date

2020-02-23, 1398/12/04

Ethics committee reference number

IR.ZAUMS.REC.1398.421

Health conditions studied

1

Description of health condition studied

Anemia

ICD-10 code

D63.1

ICD-10 code description

Anemia in chronic kidney disease

Primary outcomes

1

Description

Serum hemoglobin level

Timepoint

Before study, three month after taking drugs

Method of measurement

By measuring complete blood count in laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: receiving erythropoietin 2000 IU three times a week subcutaneously for three months plus l-carnitine placebo daily orally for three months

Category

Treatment - Drugs

2

Description

Intervention group 2: receiving erythropoietin 2000 IU three times a week subcutaneously plus l-carnitine tablet 20 mg/kg daily orally for three months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ebne Abi Taleb Hospital

Full name of responsible person

Fatemeh Attaran Kakhk

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Khalije Fars Blv, Zahedan

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ayubabedi48@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Mohsen Taheri

Street address

Vice chancellor for research, Zahedan University of Medical Sciences, Zahedan

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Dr.Taheri@zaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Fatemeh Attaran Kakhk

Position

Pediatrics resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Pediatrics resident

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Person responsible for updating data

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable