# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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 erythropietin plus l-carnitine group. Erythropietin will be given with a dose of 2000 IU three times a week subcutaneously in both groups and in the erythropietin 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 erythropietin, 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 erythropietin 2000 IU three times a week subcutaneously plus l-carnitine placebo daily orally for three months Intervention group 2: receiving erythropietin 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)

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+98 54 3329 5715

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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 erythropietin 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 erythropietin 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

**Street address**
Khalije Fars Blv, Zahedan

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## 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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Sistan-va-Balouchestan

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**Email**
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

**Street address**
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## Person responsible for scientific inquiries

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**Other areas of specialty/work**
Pediatrics

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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