

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effectiveness of oral administration of vitamin D in anemia of patients with type 2 diabetes with mild renal impairment

Protocol summary

Summary

Objective of this study is evaluation of effectiveness of oral administration of vitamin D in anemia of patients with type 2 diabetes with mild renal impairment. This study is a Phase II clinical trial, triple blind, single-center study. All patients with type 2 diabetes and anemia (Hb <12 for females and Hb,13 for males) who were referred to Imam Ali hospital clinics and their serum vitamin D levels are lower than 30 ng / ml are considered. The patients in stage 1 renal impairment with normal serum iron, ferritin, retic, LDH, ESR, TIBC, erythropoietin and unexplained anemia, after applying exclusion criteria are included. All participants provided informed consent. Patients were randomly assigned in two groups (50 patients in case group and 50 patients in control group). In case group, patients receiving vitamin D 50000 unit per week for 8 weeks and in control group patients receiving placebo for 8 weeks Finally, the hemoglobin, hematocrit levels and vitamin D for each patient was recorded at the end of the second month of treatment and outcomes of the two groups will be compared.

General information

Acronym

Effectiveness of oral administration of vitamin D in anemia of patients with type 2 diabetes with m

IRCT registration information

IRCT registration number: **IRCT2016011125951N1**

Registration date: **2016-06-14, 1395/03/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-14, 1395/03/25

Registrant information

Name

seyed mehdi hashemi

Name of organization / entity

zahedan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3342 6343

Email address

hashemimahdi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, zahedan university of medical sciences

Expected recruitment start date

2016-03-25, 1395/01/06

Expected recruitment end date

2017-03-26, 1396/01/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of oral administration of vitamin D in anemia of patients with type 2 diabetes with mild renal impairment

Public title

Effectiveness of oral administration of vitamin D in anemia of patients with type 2 diabetes with mild renal impairment

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria :all diabetic cases with anemia based on WHO criteria and mild renal impairment according to

Staging (KDIGO 2012 exclusion criteria:history of transfusion during 3 months ago/history of recent bleeding/history of recent infection during 2 months ago/history of supplement therapy/pregnancy/smoking/chronic disease of liver/kidney hypercalcemia/hyperparathyroidism/explained anemia

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization (Table of random numbers)

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Zhedan university of medical sciences Dr hesabi square, Zahedanm, Iran

City

Zahedan

Postal code

Approval date

2015-06-24, 1394/04/03

Ethics committee reference number

IR.ZAUMS.REC.1394.333

Health conditions studied

1

Description of health condition studied

anemia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Hemoglobin and vitamin D before intervention and 8 weeks after intervention

Timepoint

before intervention and at the end of intervention (end of second month)

Method of measurement

enzyme immunoassay method (EIA) [immunodiagnostic system; IDS (LTD), UK].

Secondary outcomes

1

Description

Serum 25 hydroxy vitamin D

Timepoint

8 WEEKS

Method of measurement

enzyme immunoassay method (EIA)

Intervention groups

1

Description

intervention group: 50 patients in this group receiving 50000 unit per week (pearl, Manufacturing Co. Zahravi) for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: 50 patients in placebo group receiving placebo (pearl, Manufacturing Co. Zahravi) for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

zahedan university of medical sciences

Full name of responsible person

Mahdi Hashemi

Street address

City

zahedan

2

Recruitment center

Name of recruitment center

ali ebn e abitaleb hospital

Full name of responsible person

dr seyed mahdi hashemi

Street address

ali ebn e abitaleb hospital

City

zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Zahedan University of Medical Sciences

Full name of responsible person

Houshang rafighdoust

Street address

Dr Hesabi square, zahedan university of medical sciences

City

zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

seyed mehdi hashemi

Full name of responsible person

seyed mehdi hashemi

Position

zahedan university of medical sciences

Other areas of specialty/work

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Position

Other areas of specialty/work

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00

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Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty