Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 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/hyperparathyroidesim/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 sciencesDr 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 interventin

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
Srum 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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Person responsible for updating data

Contact
Name of organization / entity
Full name of responsible person
seyed mehdi hashemi
Position
Other areas of specialty/work
Street address
City
Postal code
Phone
00
Fax
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