Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of vitamin D on HbA1c in diabetic patients aged 7-20 years with a vitamin D deficiency

Protocol summary

Summary

In this study, from December 2012 to 2013, first as case-control then interventional study, the aim is evaluation the effect of vitamin D on HbA1c in diabetic patients aged 7-20 years with vitamin D deficiency. Design: Study subjects included 62 consecutive patients with diabetes mellitus type 1 and 62 non-diabetic cases. Setting and conduct: In the first visit, height, weight, blood pressure and puberty state is recorded. The 25OHD levels in both groups and HbA1c levels in diabetic Patients will be measured. Intervention: In all diabetic Patients with insufficient levels of vitamin D or vitamin D deficiency, P, Ca, ALKP and PTH levels will be measured. Then a course of treatment with 50,000 IU of pearl vitamin D per week for ten weeks will be given and again 2 months after completion of treatment these parameters will be checked. Inclusion criteria included all diabetic type 1 Patients aged 7-20 that over the past 5 years have diabetes. Exclusion criteria included use of vitamin D supplements in the last 6 months and associated diseases (hypothyroidism, celiac disease). Main outcome measure:HbA1c levels that 2 months after the end of the intervention will be measured in diabetic Patients. Vitamin D is manufactured by the Farabi pharmaceutical. In control group with vitamin D deficiency,can be treated with pearl vitamin D but these people are not in the intervention phase of our study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013022811799N2**
Registration date: **2013-08-07, 1392/05/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-08-07, 1392/05/16

Registrant information

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Zahra Alian
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Sciences Hamedan University of Medical
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Research Assistant Hamedan University of Medical Sciences

Expected recruitment start date

2012-11-20, 1391/08/30

Expected recruitment end date

2013-11-21, 1392/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D on HbA1c in diabetic patients aged 7-20 years with a vitamin D deficiency

Public title

Vitamin D effect on the HbA1c in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- All patients aged 7-20 years with

type I diabetes 2-Over the past 5 years have diabetes 3-HbA1c level of less than 8 at the time of the study 4-Patients' vitamin D levels measured in the same season. exclusion criteria: 1-Vitamin D supplementation in the last 6 months in patients 2- Simultaneous presence of associated diseases (hypothyroidism, celiac) 3-Obesity and weight gain in the control group 4-Lack of patient cooperation.

Age
From **7 years** old to **20 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **62**

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 Hamedan University of Medical Sciences

Street address
Ethics Committee, School of Medicine, Shahid Fahmide Street

City
Hamedan

Postal code

Approval date
2013-01-01, 1391/10/12

Ethics committee reference number
349-9-35-16-پ-د

Health conditions studied

1

Description of health condition studied
Insulin-dependent diabetes mellitus

ICD-10 code
E10.9

ICD-10 code description
Insulin-dependent diabetes mellitus.Without complications

Primary outcomes

1

Description
HbA1C

Timepoint
Before and after 2 months of intervention

Method of measurement
IU, ELIZA method

Secondary outcomes

1

Description
Serum Calcium

Timepoint
before and 2 months after intervention

Method of measurement
mg/dl,Chyme Enzyme method

2

Description
Serum Phosphor

Timepoint
before and 2 months after intervention

Method of measurement
mg/dl, Chyme Enzyme method

3

Description
Alkalin phosphatase

Timepoint
before and 2 months after intervention

Method of measurement
U/L, Chyme Enzyme method

Intervention groups

1

Description
Vitamin D3 pearl 50/000 unit every 1 week for 10 weeks manufactured by the Farabi Pharmaceutical

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Endocrine Clinic, Besat Hospital

Full name of responsible person
Zahra Alian
Street address
Endocrine Clinic, Besat Hospital, Motahari Blvd.
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research , School of Medicine, Hamedan University of Medical Sciences
Full name of responsible person
Doctor Heidar Tavilani
Street address
Vice Chancellor for research , School of Medicine, Hamedan University of Medical Sciences
City
Hamedan
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 , School of Medicine, Hamedan 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
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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