

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jul 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

###### Name

Zahra Alian

###### Name of organization / entity

Sciences Hamedan University of Medical

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1264 0063

###### Email address

z.alian@umsha.ac.ir

##### 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-د-پ

## 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

Alkaline 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

z\_alian@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

School of Medicine, Hamedan University of Medical Sciences

**Full name of responsible person**

Zahra Alian

**Position**

Assistant

**Other areas of specialty/work****Street address**

Pediatric Ward 2, Besat Hospital, Motahari Blvd.

**City**

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**Postal code****Phone**

+98 81 1264 0063

**Fax****Email**

z\_alian@yahoo.com

**Web page address****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**

School of Medicine, Hamedan University of Medical Sciences

**Full name of responsible person**

Zahra Alian

**Position**

Assistant

**Other areas of specialty/work****Street address**

Pediatric Ward 2, Besat Hospital, Motahari Blvd.

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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*