

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation the effect of vitamin D supplementation on HbA1C in patients with type I diabetes mellitus and vitamin D deficiency

#### Protocol summary

##### Summary

The purpose of this study is practical and affordable and accessible solution for optimal control of diabetes and finally reducing diabetes complications. We studied patients with type I diabetes who are referred to Taleghani Hospital. These patients are about sixty people who will be invited by call and The demographic characteristics will be recorded through the questionnaires. Then sent to the laboratory. their HbA1C, 25OHD, Ca, Mg, PTH, P and Alk-p will be checked. Those with Vitamin D deficiency and insufficiency will be enrolled. Each of these individuals have been treated with vitamin D and Calcium for about twelve weeks. Then again, HbA1C and 25OHD are measured at 12th week. HbA1C levels will be compared before and after vitamin D consumption in patients with vitamin D deficiency and insufficiency. The results are analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013070113822N1**

Registration date: **2013-08-23, 1392/06/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-08-23, 1392/06/01

##### Registrant information

##### Name

Sakineh Mohammadian

##### Name of organization / entity

Golestan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 1222 7720

##### Email address

mohammadian@goums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

public - Golestan University of Medical Sciences

##### Expected recruitment start date

2013-04-21, 1392/02/01

##### Expected recruitment end date

2013-05-22, 1392/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation the effect of vitamin D supplementation on HbA1C in patients with type I diabetes mellitus and vitamin D deficiency

##### Public title

Evaluation the effect of vitamin D supplementation in patients with type I diabetes mellitus and vitamin D deficiency

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: type I diabetic and vitamin D deficiency patients; normal liver function; normal renal function. exclusion criteria: Irregular use of calcium and vitamin D during the study; hypercalciuria with nephrolithiasis .

##### Age

To **18 years** old

##### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## 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

Golestan University of Medical Sciences

##### Street address

Golestan University of Medical Sciences, Shast Kola Road, Gorgan, Golestan

##### City

Gorgan

##### Postal code

#### Approval date

2012-10-31, 1391/08/10

#### Ethics committee reference number

19108102111

## Health conditions studied

### 1

#### Description of health condition studied

diabetes (mellitus):type I

#### ICD-10 code

E10

#### ICD-10 code description

diabetes (mellitus):type I

### 2

#### Description of health condition studied

Vitamin D deficiency, unspecified

#### ICD-10 code

E55.9

#### ICD-10 code description

Vitamin D deficiency, unspecified

## Primary outcomes

### 1

#### Description

25OHD

#### Timepoint

before intervention, three months after intervention

#### Method of measurement

blood sampling, ng/dl

### 2

#### Description

HbA1C

#### Timepoint

before intervention, three months after intervention

#### Method of measurement

blood sampling

## Secondary outcomes

### 1

#### Description

mg

#### Timepoint

before intervention

#### Method of measurement

blood sampling, Mg/dl

### 2

#### Description

p

#### Timepoint

before intervention

#### Method of measurement

bleeding sample/ Mg/dl

### 3

#### Description

pth

#### Timepoint

before intervention

#### Method of measurement

ng/l

### 4

#### Description

ca

#### Timepoint

before intervention

#### Method of measurement

blood sampling, Mg/dl

## Intervention groups

## 1

### Description

for all patients with vitamin D deficiency, single dose of vitamin D(300,000 unit) will be injected intramuscular. Non-cooperative patients treated weekly with pearl vitamin D (50,000unit) orally for eight weeks. for avoiding Hungry Bone, syrup calcium(40 Mg/Kg/Day) will be consumed for about three months.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleghani children hospital

##### Full name of responsible person

Dr. Sakineh Mohammadian, pediatrician, associated professor

##### Street address

Taleghani children hospital, Janbazan Blv., Gorgan

##### City

Gorgan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Golestan University of Medical Sciences

##### Full name of responsible person

Dr. Mohamad Jafar Golalipoor

##### Street address

Golestan University of Medical Sciences, Research and Technology Department, Shastkola Road

##### City

Gorgan

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Golestan 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

Golestan university of Medical Science

#### Full name of responsible person

Dr. Nasrin Fatahi

#### Position

resident, project executer

#### Other areas of specialty/work

#### Street address

Taleghani hospital, Janbazan Blv.r, Gorgan

#### City

Gorgan

#### Postal code

#### Phone

+98 17 1222 7720

#### Fax

#### Email

nfty3063@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Neonatal and Children Health Research Center,  
Golestan University of Medical Science

#### Full name of responsible person

Dr. Sakineh Mohammadian, pediatrician, associated professor

#### Position

pediatrician, associated professor

#### Other areas of specialty/work

#### Street address

Talghani Hospital, Janbazan Blv., Gorgan

#### City

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+98 17 1222 7720

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saminmoh@yahoo.com

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Golestan University of Medical Sciences

#### Full name of responsible person

Dr. Nasrin Fatahi

#### Position

Resident, project executer

#### Other areas of specialty/work

#### Street address

Talghani Hospital, Janbazan Blv, Gorgan

#### City

Gorgan

#### Postal code

**Phone**

+98 17 1222 7720

**Fax**

**Email**

nfty3063@yahoo.com

**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*