

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

Gorgan

Postal code

Phone

+98 17 1222 7720

Fax

Email

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