

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The evaluation of the effect of administering of vitamin D on glycemic control in pediatric patients with type1 Diabetes Mellitus

Protocol summary

Study aim

- Determination of vitamin D supplementation effect on glycemic control in pediatrics with type 1 diabetes

Design

42 patients with type 1 diabetes mellitus aged 1 to 18 years, without control group and without blinding in a clinical trial, phase 3

Settings and conduct

Mofid Hospital Endocrinology and Metabolism Clinic, Tehran

Participants/Inclusion and exclusion criteria

Age range from one to eighteen years; given that the goals of glycemic control vary for different ages, age range is important; type 1 diabetes; having at least one year of type 1 diabetes; vitamin D deficiency.

Intervention groups

Vitamin D administration for children with type 2 diabetes

Main outcome variables

Fasting and non-fasting sugars, daily insulin intake, HbA1c

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190917044806N1**

Registration date: **2020-05-30, 1399/03/10**

Registration timing: **retrospective**

Last update: **2020-05-30, 1399/03/10**

Update count: **0**

Registration date

2020-05-30, 1399/03/10

Registrant information

Name

Arezoo Shirzani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2232 1040

Email address

shirzani.arezoo@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

2018-06-22, 1397/04/01

Actual recruitment end date

2019-08-03, 1398/05/12

Trial completion date

2019-09-23, 1398/07/01

Scientific title

The evaluation of the effect of administering of vitamin D on glycemic control in pediatric patients with type1 Diabetes Mellitus

Public title

The evaluation of effect of administration of vitamin D on glycemic index in patient with Diabetes Mellitus type1(DM1)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age 1-18 years; catching Diabetes Mellitus type1; Having at least one year of type 1 diabetes; vitamin D deficiency.

Exclusion criteria:

Take vitamin D supplements in the past 6 months No

underlying kidney disease Patient non-cooperation in clinic follow-up

Age

From **1 year** old to **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **40**

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 Medical School Research -
Shahid Beheshti University of Medical Sciences

Street address

Tehran, Quds Town (West), between South Flamak
and Zarafshan, Iran Sima St. - Central Office of
Ministry of Health and Medical Education, Block A,
13th Floor

City

Tehran

Province

Tehran

Postal code

11111111111

Approval date

2019-07-02, 1398/04/11

Ethics committee reference number

IR.SBMU.MSP.REC.1398.339

Health conditions studied

1

Description of health condition studied

Type 1 diabetes in children

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes

1

Description

HbA1C

Timepoint

At baseline (before intervention) and 3 and 6 months
after vitamin D intake

Method of measurement

Laboratory sample

Secondary outcomes

1

Description

Fasting blood sugar

Timepoint

At baseline (before intervention) and 3, 6 months after
vitamin D intake

Method of measurement

Enzymatic

2

Description

Post prandial blood sugar

Timepoint

At baseline (before intervention) and 3, 6 months after
vitamin D intake

Method of measurement

Enzymatic

3

Description

Daily insulin intake

Timepoint

At baseline (before intervention) and 3, 6 months after
vitamin D intake

Method of measurement

Enzyme-linked immunosorbent

Intervention groups

1

Description

Intervention group: Vitamin D (cholecalciferol), 50,000
units, weekly for 4-6 weeks from Zahrawei Company and
then 1000 units daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mofid pediatric specialty hospital
Full name of responsible person
Arezoo Shirzani
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Shariati Street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
دکتر آرزو شیرزانی
Position
دانشجو
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
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Person responsible for scientific inquiries

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Professor
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Person responsible for updating data

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student

Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable