Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Street address
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
Shahid Beheshti University of Medical Sciences

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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 شیرزنی

Position
دانشجو

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

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Person responsible for scientific inquiries

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Marjan Shakiba

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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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