

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of vitamin D on Insulin requirement in children with diabetes type 1 and vitamin D deficiency

Protocol summary

Summary

objective: In this clinical trial the effect of vitamin D Supplementation on insulin dose in diabetic children will be evaluated. Design: The Sample included 60 children aged 5 to 15 years with type I diabetes presenting to pediatric endocrinology clinic. Setting and participants: Within the first visit, Height, weight, Blood pressure and maturity status are evaluated. Serum levels of 25 (OH) D , TSH, Ca, p, Alkp and HbA1C will be measured. In diabetic cases who have Vitamin D deficiency or insufficiency, dose of insulin will be measured. Inclusion major eligibility criteria: children with type 1 diabetes and vitamin D deficiency. Exclusion criteria: Vitamin D supplementation in the last 6 months Intervention: In the second phase, cases with insufficient levels of vitamin D or vitamin D deficiency are treated with 50,000 IU of vitamin D Pearl 10 per week to 10 weeks and again, after the end of treatment, serum levels of vitamin D and HbA1C and insulin dose will be evaluated. Main outcome measure variables: If this study clinically and statistically lead to significant results, Vitamin D can be measured in diabetic children and with treatment in the event of vitamin D deficiency, decrease insulin intake and in long time can reduce the financial burden on the families of people with diabetes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014120111799N3**

Registration date: **2015-03-14, 1393/12/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-14, 1393/12/23

Registrant information

Name

Zahra Alian

Name of organization / entity

Sciences Hamedan University of Medical

Country

Iran (Islamic Republic of)

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+98 81 1264 0063

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z.aliان@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research And Technology

Expected recruitment start date

2014-06-21, 1393/03/31

Expected recruitment end date

2015-08-22, 1394/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D on Insulin requirement in children with diabetes type 1 and vitamin D deficiency

Public title

Effect of vitamin D on Insulin requirement

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion Criteria: 1) Diabetic cases 5-15 years old that referred to endocrinology clinic 2) 6 months after the diagnosis of type 1 diabetes Exclusion Criteria: 1) Vitamin D supplementation in the last 6 months 2) The simultaneous existence of associated diseases

(hypothyroidism) 3) Lack of cooperation 4) Regime change in the treatment of diabetes

Age

From **5 years** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

Shahid Fahmide Street

City

Hamedan

Postal code

Approval date

2015-01-24, 1393/11/04

Ethics committee reference number

5433/9/35/16/پ

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E10-E11-E1

ICD-10 code description

Diabetes mellitus

Primary outcomes

1

Description

Insulin Dose

Timepoint

Before intervention, 3 Months after the intervention

Method of measurement

Unit/ Syrange Insulin 100 unit/ penfile insulin

Secondary outcomes

1

Description

Blood Glucose

Timepoint

Before intervention,3 months after the intervention

Method of measurement

mg/dl/ECL method

Intervention groups

1

Description

Pearl Vitamin D3,50000 unit,Manufacturing of Razi Pharmaceutical Company,each week one for 10 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Clinic

Full name of responsible person

Zahra Alian

Street address

Pediatric Ward 2, Besat Hospital

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Hamedan University of Medical Sciences

Full name of responsible person

Doctor Saeed Bashirian

Street address

Shahid Fahmideh Blvd, Medicine School

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, 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,Sciences Hamedan University Of
Medical

Full name of responsible person

Zahra Alian

Position

Assistant

Other areas of specialty/work

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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