Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Effects of a vitamin D analog on glycemic control and immune response in type 1 diabetic children

Protocol summary

Summary

At the time of type 1 diabetes diagnosis, although the majority of beta-cells have been destroyed, some still produce insulin. A treatment that could protect beta-cell function or decrease autoimmune destruction would provide important progress in type 1 diabetes therapy. Vitamin D has been known as an immunomodulator in this disease, which blockades beta-cells destruction. In children with type 1 diabetes, vitamin D treatment produces moderate protective effects on residual beta-cell function. However, limited doses can be used because of its hypercalcemic effect. This study investigated whether treatment with a vitamin D analog (1-α-hydroxivitamin D3) or alfacalcidol, can improve glycemic control and beta-cell preservation, as well as improvements in immune responses. In this single-blind and placebo-controlled clinical trial, 60 patients (aged 8-18 years) with recent-onset type 1 diabetes will be randomized to alfacalcidol (2 * 0.25 microgram/day) or placebo, and will follow up for 6 months. All patients will receive conventional insulin therapy, and insulin dosage will be adjusted every two weeks. Insulin requirement, as well as serum 25(OH)D, fasting C-peptide (FCP), hemoglobin A1C (HbA1C), interleukin-1β (IL-1β), interleukin-2 (IL-2), transforming growth factor β1 (TGF-β1), interferon-gamma (IFN-γ), and glutamic acid decarboxylase (GAD65) autoantibody will be assessed at baseline, and again 3 months and 6 months after the intervention. The alfacalcidol and placebo groups will be compared across time points during 6 months of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205159753N1**
Registration date: **2012-06-02, 1391/03/13**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2012-06-02, 1391/03/13

Registrant information

Name

Asal Ataie-Jafari

Name of organization / entity

Endocrinology & Metabolism Research Institute, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8490 2477

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Recruitment status

Recruitment complete

Funding source

Endocrinology & Metabolism Research Center, Tehran University of Medical Sciences

Expected recruitment start date

2012-03-01, 1390/12/11

Expected recruitment end date

2012-07-01, 1391/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of a vitamin D analog on glycemic control and immune response in type 1 diabetic children

Public title

Effects of a vitamin D analog in type 1 diabetic children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age 8-18 years; Consecutively diagnosed as having T1DM according to the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus criteria; Without DKA; Duration of clinical disease (since the beginning of insulin therapy) less than 8 weeks; Without any medical co-morbidities or any other major chronic disease; Being on a stable diabetic diet therapy at least since 1 week ago Exclusion criteria: Cholecalciferol, calcium, multi-vitamin or mineral supplementation during the previous 3 months; Consuming some vitamin D-fortified foods; Hypercalcemia defined as total serum calcium higher than 10.8 mg/dl, at baseline or during follow-up.

Age

From **8 years** old 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)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Endocrinology & Metabolism Research Center Institute

Street address

5th floor, Shariati Hospital, North Karegar Avenue

City

Tehran

Postal code

1411413137

Approval date

2011-02-10, 1389/11/21

Ethics committee reference number

E-00100

Health conditions studied

1

Description of health condition studied

type 1 diabetes

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Serum fasting C-peptide

Timepoint

months 0, 3, and 6 after intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

Dose of insulin requirement

Timepoint

months 0, 3, and 6 after intervention

Method of measurement

Adjusted dose of insulin according to patients' blood glucose records

Intervention groups

1

Description

Intervention group, alfacalcidol, 0.25 microgram, 2 times daily for 6 months

Category

Treatment - Drugs

2

Description

Control group, placebo capsules, 2 times daily for 6 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital of Tehran University of Medical Sciences, and Children Medical Center / Tehran Uni

Full name of responsible person

Asal Ataie-Jafari
Street address
North Karegar Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Endocrinology & Metabolism Research Institute, Tehran University of Medical Sciences
Full name of responsible person
Professor Bagher Larijani
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5th floor, Shariati hospital, North Karegar Avenue
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Endocrinology & Metabolism Research Institute, Tehran 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

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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*