

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Supplementation effect of vitamin D on endothelial function in patients with type 1 diabetes

Protocol summary

Summary

The main purpose of this study is to survey the supplementation effect of vitamin D on endothelial function in patients with type 1 diabetes. This is a double blind randomized placebo-controlled clinical trial. Ultrasonography will be performed in a single center for the patients who referred from two endocrinologists. Study population includes 72 patients who equally divided to case and control group. Inclusion criteria for the patients are as follows: confirmed type 1 diabetes mellitus, age range of 5 to 20 years old, without vitamin D deficiency (vitamin D level > 30 nmol/L) and disturbed FMD. Patients with HbA1c $\geq 8\%$, hepatic dysfunction or malignancy and uncontrolled hypertension will be excluded. Patients in case group will receive 1000 IU of vitamin D every day for 12 weeks. In the same period of time, the placebo will be taken by control group. For the assessment of arterial function, brachial artery diameter of each patient is measured by two radiologists separately. In this regard, FMD will be calculated two times at the initiation (before intervention) and the end (after 12 weeks) of the study period using the following formula: $FMD = (D1 - D0) / D0 \times 100$

General information

Acronym

FMD - Flow Mediated Dilatation

IRCT registration information

IRCT registration number: **IRCT2016112331062N1**

Registration date: **2017-01-27, 1395/11/08**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-01-27, 1395/11/08

Registrant information

Name

zahra mardanshahi

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 11 3325 5348

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mardanshahi56@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazanadarn University of Medical Sciences and Daana Pharmaceutical Company will fund this project

Expected recruitment start date

2017-02-03, 1395/11/15

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Supplementation effect of vitamin D on endothelial function in patients with type 1 diabetes

Public title

The Supplementation effect of vitamin D on arterial function in patients with type 1 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: - Confirmed Type 1 diabetes mellitus - Age range of 5 to 20 years old - Without vitamin D deficiency (level of 25-hydroxyvitamin D > 30 nmol/L) -

With disturbed FMD (2% change in FMD) Exclusion
Criteria: - HbA1c $\geq$ 8% - Hepatic dysfunction or
malignancy - Uncontrolled hypertension ($>140/90$
mmHg)

Age

From **5 years** old to **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Mazandaran University of Medical
Sciences

Street address

Moallem square, Mazandaran University of Medical
Sciences

City

Sari

Postal code

Approval date

2016-12-28, 1395/10/08

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.2616

Health conditions studied

1

Description of health condition studied

diabetes mellitus type I

ICD-10 code

E10

ICD-10 code description

diabetes (mellitus): brittle juvenile-onset ketosis-prone
type I

Primary outcomes

1

Description

flow mediated dilation of the brachial artery

Timepoint

Initial of the study (Before intervention) and end of the
study (After 12 weeks)

Method of measurement

FMD measurement in this study will be done based on
ACC guideline. The subject is positioned supine for 10
minutes with the arm in a comfortable position. First,
anterior-posterior diameter of the right brachial artery is
measured 3-5 centimeter above the antecubital fossa by
using a Doppler Ultrasound probe and measurement
location will be marked on the skin. For the next step, a
sphygmomanometric cuff is placed on the forearm below
the arterial scan location. The cuff is inflated to at least
250 mm Hg to occlude arterial inflow for 5 minutes. This
causes ischemia of downstream resistance vessels. 45 -
60 seconds after cuff dilation, the longitudinal image of
the brachial artery is recorded again on the same
location as before to measure its anterior-posterior
diameter. In the response to increase blood flow after
induced ischemia, brachial artery dilates and this dilation
depends on arterial endothelium.

Secondary outcomes

1

Description

Fasting blood sugar

Timepoint

Begining of the study (Before the intervention) and End
of the study (48 hours after final medicine usage)

Method of measurement

Blood samples from all patients will be sent to the
laboratory for glucose analysis

Intervention groups

1

Description

Patients in the in intervention group will receive 1000 IU
of vitamin D every day for 12 weeks.

Category

Treatment - Drugs

2

Description

placebo will be taken by the control group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bouali Sina Hospital

Full name of responsible person

Zahra Mardanshahi

Street address

Bouali Sina hospital, Pasdaran Blvd.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Daana Pharmaceutical Company

Full name of responsible person

Reza Jalali Milani

Street address

No. 3, 6th block, In front of Tehran clinic, Ghaem
Magham Farahani St

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Daana Pharmaceutical Company

Proportion provided by this source**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

2

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Bagher Montazeri

Street address

Moallem square, Mazandaran University of Medical
Sciences

City

Sari

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mazandaran University of Medical Sciences

Proportion provided by this source**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

Mazandaran University of Medical Sciences

Full name of responsible person

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Person responsible for scientific 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