

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of vitamin D and synbiotic co-supplementation on HbA1c, Metabolic Profile, Serum Concentration of some biomarkers of inflammation, oxidative stress and quality of life in patients with type 1 diabetes

Protocol summary

Study aim

The effects of vitamin D and synbiotic co-supplementation on HbA1c, Metabolic Profile and Serum Concentration of some biomarkers of inflammation, oxidative stress and quality of life in patients with type 1 diabetes

Design

Clinical Trial with Control Group, Parallel Groups, Double Blind, Randomized

Settings and conduct

Patients, who are eligible according to Inclusion and exclusion criteria, would be invited to Isfahan Endocrine and Metabolism Research Center . For randomization, random blocks with quadrilateral blocks will be used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Signed Consent Written Consent 2. HbA1c above 7% 3. Aged 65-18 years 4. Duration of more than 1 Year 5. Treatment with Multiple Injections of Insulin. Exclusion criteria: 1. Pregnancy 2. Other autoimmune diseases 3. Hyperglycemia leads to ketoacidosis over the past month 4. Use of mixed insulins 5. Use Supplements Related to the Study

Intervention groups

Individuals in the Intervention Group will Receive a 50000 IU Vitamin D supplementation every 2 Weeks and also They will Receive 1 Synbiotic capsules per day for 12 Weeks. Individuals in the Control Group will Receive Vitamin D Pelacebo every 2 Weeks and also They will Receive 1 Synbiotic Placebo per Day for 12 Weeks.

Main outcome variables

The Primary Outcomes of this Study are Hemoglobin A1C, Serum 25 hydroxyvitamin D Levels and Total Insulin, Tumour Necrosis Factor α , High Sensitivity C-Reactive Protein, Total Antioxidant Capacity, Malondialdehyde .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180127038521N1**

Registration date: **2018-04-02, 1397/01/13**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-14, 1398/06/23**

Update count: **1**

Registration date

2018-04-02, 1397/01/13

Registrant information

Name

Fatemehsadat Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4852

Email address

amiri.fs@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-06, 1396/12/15

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of vitamin D and synbiotic co-supplementation on HbA1c, Metabolic Profile, Serum Concentration of some biomarkers of inflammation, oxidative stress and quality of life in patients with type 1 diabetes

Public title

The Effect of Vitamin D and Synbiotic Supplementation in Type 1 Diabetes.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Desire to cooperate and sign a written informed consent
HbA1c more than 7% (Based on the American Diabetes Association's Guidelines to Uncontrolled Diabetes)
Duration of the Disease more than 1 Year Treatment with Multiple Injections of Insulin (Regular, NPH, Glargine, Detemir, Aspartate, Glucosin, Lispro)

Exclusion criteria:

Pregnancy autoimmune disorders (celiac, hashimoto, asthma, allergies, ..) Severe Hypoglycemia so that the Person Needs Another Person's Help to Resolve the Condition (3 Times or more During the Last Year, 1 or more in the Last 3 Months) Hyperglycemia Leads to Ketoacidosis over the Past Month Use of Mixed Insulin (Novomix and 70/30) taking vitamin D supplements (oral and Injection) taking synbiotic supplement taking calcium-vitamin D taking multivitamin-minerals taking antioxidant or anti-inflammatory such as vitamins E and C supplements, omega-3 fatty acids taking Consumption of Vitamin D-Enriched Foods over the Past 3 Months Severe Complications of Diabetes (Advanced Macrovascular and Microvascular Complications Including Major Cardiovascular Disorders (Acute Myocardial Infarction, Coronary Artery Bypass, Stroke and Peripheral Arterial Disease), Severe Nephropathy) cancer hepatic failure end-stage renal disease stroke with cognitive deficiency psychotic disorder bipolar disorder severe substance abuse mental retardation active infection rheumatoid arthritis inflammatory bowel disease Special Medicines (Hormone Therapy) Taking psychotropic drugs taking immunosuppressive medications over the past 3 months

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

For Randomization, the Permuted Block Randomization Method will be Used Blocks with the Size of Four . According to the Sample Size 114, 29 Blocks will be Produced Using the Online Site (www.sealedenvelope.com).

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to Apply Concealment in the Randomization Process, Unique Codes which are Generated by the Software will be Used on the Supplements Box., By Entering each Person into the Study According to the Generated Sequence, the Supplement Box where the Code is Registered on will be Assigned to the Individual. During the Study, the Randomization List is Provided to the Statistic Consultant and the Participants, the Project Author and all those who Participate in the Measurement of the Indices will not be Informed of the Assigned Groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Tehran, Hemat Highway, Next to Milad Tower, Iran University of Medical Sciences

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۱۴۴۹۶۱۴۵۳۵

Approval date

2017-10-27, 1396/08/05

Ethics committee reference number

IR.IUMS.FMD.REC 1396.۹۵۱۱۳۳۳۰۰۱

Health conditions studied

1

Description of health condition studied

Type 1 Diabetes

ICD-10 code

E10

ICD-10 code description
Type 1 diabetes mellitus

Primary outcomes

1

Description

Hemoglobin A1c

Timepoint

Before and After Intervention

Method of measurement

Biochemical Test

2

Description

Serum Level of 25 Hydroxyvitamin D

Timepoint

Before and After Intervention

Method of measurement

Biochemical Test

3

Description

Total Insulin Demand

Timepoint

Before and After Intervention

Method of measurement

Questionnaire

4

Description

High Sensitivity C-Reactive Protein

Timepoint

Before and After Intervention

Method of measurement

Chemiluminescence

5

Description

Tumour Necrosis Factor α

Timepoint

Before and After Intervention

Method of measurement

ELISA

6

Description

Total Antioxidant Capacity

Timepoint

Before and After Intervention

Method of measurement

Colorimetric

7

Description

Malondialdehyde

Timepoint

Before and After Intervention

Method of measurement

Colorimetric

Secondary outcomes

1

Description

Fasting Blood Glucose

Timepoint

Before and After Intervention

Method of measurement

Biochemical Test

2

Description

Triglyceride

Timepoint

Before and After Intervention

Method of measurement

Photometric

3

Description

Total Cholesterol

Timepoint

Before and After Intervention

Method of measurement

Photometric

4

Description

HDL-Cholesterol

Timepoint

Before and After Intervention

Method of measurement

Enzymatic Method

5

Description

LDL-Cholesterol

Timepoint

Before and After Intervention

Method of measurement

Enzymatic Method

6

Description

Systolic Blood Pressure

Timepoint

Before and After Intervention

Method of measurement

Mercuric Barometer

7

Description

Diastolic Blood Pressure

Timepoint

Before and After Intervention

Method of measurement

Mercuric Barometer

8

Description

Interleukin 17

Timepoint

Before and After Intervention

Method of measurement

ELISA

9

Description

Insulin Resistance

Timepoint

Before and After Intervention

Method of measurement

Estimated Glucose Disposal Rate

10

Description

Weight

Timepoint

Before and After Intervention

Method of measurement

scale

11

Description

Body Mass Index

Timepoint

Before and After Intervention

Method of measurement

Calculation

12

Description

Waist Circumference

Timepoint

Before and After Intervention

Method of measurement

Measuring Tape

13

Description

Waist / Hip Ratio

Timepoint

Before and After Intervention

Method of measurement

Calculation

14

Description

Injected Insulin Dose

Timepoint

Before and After Intervention

Method of measurement

Questionnaire

15

Description

Number of Insulin Injections

Timepoint

Before and After Intervention

Method of measurement

Questionnaire

16

Description

Hand Grip

Timepoint

Before and After Intervention

Method of measurement

Dynamometer

17

Description

Quality-of-Life

Timepoint

Before and After Intervention

Method of measurement

Questionnaire Quality-of-Life

18

Description

Mood

Timepoint

Before and After Intervention

Method of measurement

Questionnaire Beck Depression

19

Description

Mean Arterial Pressure

Timepoint

Before and After Intervention

Method of measurement

Calculation

20

Description

Hip circumference

Timepoint

Before and After Intervention

Method of measurement

Measuring Tape

21

Description

Bloating condition

Timepoint

Before and After Intervention

Method of measurement

Questionnaire

22

Description

Body fat percentage

Timepoint

Before and After Intervention

Method of measurement

inbody scale

Intervention groups

1

Description

Intervention group: The Duration of the Intervention will be 3 Months. the Intervention Group will be given one Vitamin D 50,000 IU (Manufactured by Zahravi Company) every 2 weeks and One Capsule of Synbiotic (Manufactured by Zisttakhmir Company) Per Day (Containing probiotic species Lactobacillus Casei, Lactobacillus Acidophilus, Lactobacillus Rhamnosus, Lactobacillus Bulgaricus, Bifidobacterium Bro, Bifidobacterium Longum, Streptococcus Thermophilus CFU / gr1010 and Fructo-Oligosaccharide (38.5 mg)) During the 3 Months of Intervention. In order to Maintain Cooling Chain, each Patient is Provided with an Ice Bag for Carrying Synbiotic Supplementation.

Category

Treatment - Other

2

Description

Control group: The Intervention Duration will be 3 Months. Individuals in the Control Group will Receive Vitamin D Pelacebo (Manufactured by Zahravi Company) every 2 weeks . Vitamin D Pelacebo Contains Lactose. They will also Receive 1 Synbiotic Placebo per day for 12 weeks (Manufactured by Zisttakhmir Company). Synbiotic Placebo Contains Lactose, Magnesium Stearate, Talc, Silicon Dioxide.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan province Endocrine and Metabolism Research Center

Full name of responsible person

Ali Ebrahimkhani, Sakineh Bakhshizadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Seyed Kazem Malakooti

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Tower, Hemmat Highway, Tehran

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Grant name

Vice Dean of Research of Iran University of Medical
Science

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Fatemeh-Sadat Amiri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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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

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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