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)

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+98 21 8670 4852

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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, Glulosin, Lispro)

Exclusion criteria:
Pregnancy autoimmune disorders (celiac, hashimato, 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

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2017-10-27, 1396/08/05

Ethics committee reference number
IR.IUMS.FMD.REC 1396.۹۵۱۱۳۲۳۰۰۱

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
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Full name of responsible person
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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
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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