Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of synbiotic supplementation on glycemic factor, lipid profile, Total antioxidant capacity and serum inflammatory factors in patients with type 1 diabetes.

Protocol summary

Study aim
Determination of the Effect of Synbiotic Supplementation on Glycemic Factor, Lipid Profile, Total Antioxidant Capacity and Serum Inflammatory Factors in Patients with Type 1 Diabetes

Design
In this double-blind trial study, 50 subjects were selected based on entry and exit criteria for participation in this study. Using simple random sampling, they were randomly divided into two groups of 25 intervention and control group.

Settings and conduct
This is a clinical trial study done on type 1 diabetic patients referred to an endocrinologist clinic in 1397. The proposed patients are coded by a third party health care provider who does not know anything about the research, and researchers and patients also do not have information about the contents of the packages.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Type 1 diabetes. Exit criteria: Unwillingness to participate in the study, kidney disease, coronary arteries, acute and chronic lung inflammation, short stomach cyst syndrome, allergy, travel more than 2 weeks, smokers, use of food supplements, anti-inflammatory drugs, use of any antioxidant supplements in the last 3 months, use of medications Immune suppressants, follow special diets, change diet or decide to lose weight

Intervention groups
Patients (50 people) are randomly divided into two groups of 25. In the intervention group, 1 gramme of synbiotic supplement from the Parsi Lakt Shiraz Company (cfu 109 Lactobacillus spurogenesis and cfu 1010 Bifidobacterium as probiotic and inulin as a periwist) with a glass of water once a day after lunch for a period of 8 weeks. In the control group, patients receive 1 g of starch with a glass of water once a day after lunch for 8 weeks.

Main outcome variables
Fasting blood glucose, serum insulin, HbA1c, lipid factor TG, Chol-T, LDL-c, HDL-c, total antioxidant capacity (TAC) and inflammatory factors

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180310039020N1**
Registration date: **2018-05-11, 1397/02/21**
Registration timing: **prospective**

Last update: **2018-05-11, 1397/02/21**
Update count: **0**

Registration date
2018-05-11, 1397/02/21

Registrant information

Name
Mona Jamalvandi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 25 3777 8206

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-22, 1397/04/01

Expected recruitment end date
2018-08-23, 1397/06/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of synbiotic supplementation on glycemic factor, lipid profile, Total antioxidant capacity and serum inflammatory factors in patients with type 1 diabetes.

Public title
Effect of synbiotic in diabetes
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
All of type 1 diabetes who have at least 1 year of diagnosis According to BMI for age chart, their body mass index is below 95%
Exclusion criteria:
Unwillingness of patients to participate in the study Renal diseases, coronary arteries, acute and chronic inflammation of the lungs, short stomach cyst syndrome, allergies, pregnancy, lactation Traveling for more than 2 weeks Smokers, the use of food supplements, anti-inflammatory drugs, the use of any antioxidant supplements in the last 3 months, the use of immunosuppressive drugs Follow certain diets, change your diet or decide to lose weight
Age
From **4 years** old to **18 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
First of all, individuals who have the characteristics necessary to enter the study are usually taken from a non-random sample using a simple sampling method. Then, randomization is done between study groups. In this study, a block randomization method (block 4) is used. One of the study colleagues who did not have blindfolded, named synbiotic and placebo with the letters A and B (for example). Then, the researcher distributed A and B packages among the patients referring to the study in the office by random blocking (ABAB, BABA, AABB, ABBA, ABBA, BAAB) by randomized blocking (First person A, Second person B, third person A, fourth person B, ...). Then, blocks are created so that blocks are randomly selected to reach the required sample size.
Blinding (investigator's opinion)
Double blinded
Blinding description
To blind the study, it is given to a powder control group that is similar in appearance to the supplement in the treatment group (intervention), which has no effective substance (placebo or placebo). In this study, coding will be done by a third person from health care providers who do not know anything about this research, and researchers and patients will not be aware of the contents of the packets.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Ethics Committee of the Jundishapur University of Medical Sciences Ahwaz
Street address
Iran, Khuzestan, Ahvaz, Ave. Golestan, Jundishapur University of Medical Sciences, Ahvaz, Iran
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2018-03-03, 1396/12/12
Ethics committee reference number
IR.AJUMS.REC.1396.1032

Health conditions studied

1

Description of health condition studied
type1 Diabetes
ICD-10 code
E10
ICD-10 code description
Type 1 diabetes mellitus

Primary outcomes

1

Description
Blood sugar in the morning
Timepoint

Before and after the intervention

Method of measurement

Use of the kit in an enzymatic method

2

Description

HbA1C

Timepoint

Before and after the intervention

Method of measurement

Use of the kit in an enzymatic method

3

Description

LDL cholesterol

Timepoint

Before and after the intervention

Method of measurement

Use of the kit in an enzymatic method

4

Description

HDL cholesterol

Timepoint

Before and after the intervention

Method of measurement

Use of the kit in an enzymatic method

5

Description

Tri glyceride

Timepoint

Before and after the intervention

Method of measurement

Use of the kit in an enzymatic method

6

Description

Total cholesterol

Timepoint

Before and after the intervention

Method of measurement

Use of the kit in an enzymatic method

7

Description

TNF-α

Timepoint

Before and after the intervention

Method of measurement

Eliza

8

Description

hs-CRP

Timepoint

Before and after the intervention

Method of measurement

Eliza

9

Description

TAC

Timepoint

Before and after the intervention

Method of measurement

Eliza

10

Description

Insulin serum

Timepoint

Before and after the intervention

Method of measurement

Elisa

11

Description

Insulin resistance (HOMA-IR)

Timepoint

Before and after the intervention

Method of measurement

Elisa

12

Description

IL-6

Timepoint

Before and after the intervention

Method of measurement

Elisa

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group consumes 1 g of synbiotic supplement with a glass of water once a day after lunch for 8 weeks.

Category

Other

2

Description

Control group: In the control group, patients take 1 g of starch with a glass of water once a day after lunch for 8 weeks.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Private Doctor Endocrinologist

Full name of responsible person
Mona jamalvandi

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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

Grant code / Reference number

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

Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Mona jamalvandi

Position
Master's Degree in Nutrition Sciences

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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Person responsible for updating data

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Latest degree

Bachelor

Other areas of specialty/work

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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