Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of synbiotic on blood glucose level and HbA1c in children with type 1 diabetes. A parallel, double-blind, randomized clinical trial

Protocol summary

Study aim

Determination the effect of synbiotic on blood glucose level and HbA1c in children with type 1 diabetes

Design

Clinical trial with control group, parallel groups, double-blind, randomized, phase 3 on 86 patients. SAS software version9 was used for randomization.

Settings and conduct

In this study, we will investigate the effect of KidiLact (a synbiotic product of Zisttakhmir Company) on type 1 diabetes in children aged 4-18 years referred to 17 Shahrivar Hospital. For 12 weeks, in addition to injectable insulin, the intervention group was given synbiotics and the control group was given a placebo. Sampling is done by random blocking method and block size of 4 with 1: 1 allocation ratio. Double blinding is done for the participants and the main researcher.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 4-18 Years; At least 6 Months after the diagnosis of diabetes; Being treated with injectable insulin Exclusion criteria: Renal disease; Gastrointestinal disease; Cardiovascular disease; Pulmonary disease; Taking antibiotics or NSAIDs and immunosuppressants during the last month; Taking products containing probiotics and synbiotics or antioxidants in the last month

Intervention groups

The intervention group initially takes half a Kidilact sachet(0.5 g) - the product of Zisttakhmir Company - daily for 2 weeks, and if they have no gastrointestinal side effects, will use one sachet daily for the remaining 10weeks. The control group initially takes half a sachet (0.5 g) of placebo for 2weeks, and if they have no GI side effects, they receive one sachet daily for the remaining 10weeks.

Main outcome variables

Blood Glucose level ; Glycated Hemoglobin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210712051866N1**
Registration date: **2022-05-04, 1401/02/14**
Registration timing: **prospective**

Last update: **2022-05-04, 1401/02/14**
Update count: **0**

Registration date

2022-05-04, 1401/02/14

Registrant information

Name

setila dalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 9002

Email address

setiladalili1346@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of synbiotic on blood glucose level and HbA1c in children with type 1 diabetes. A parallel, double-blind, randomized clinical trial

Public title
Effect of synbiotic on diabetes control
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Girls and Boys 4-18 Years At least 6 Months after the Diagnosis of Diabetes Being Treated with Injectable Insulin Fasting Blod Sugar (FBS) ≥ 126 mg/dl Glocuse, 2 hour Post Prandial (2hpp) ≥ 200 mg/dl Glycated Hemoglobin (HbA1c) ≥ 6.5% Blood Sugar (BS) ≥ 200 mg/dl Along with Polydipsia and Polyuria
Exclusion criteria:
Renal disease Gastrointestinal disease Cardiovascular disease (CVD) Pulmonary disease Taking antibiotics, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), immunosuppressants during the last month; Taking products containing probiotics and synbiotics or antioxidants in the last month
Age
From **4 years** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **86**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to Randomize the treatment between the groups, Permuted Block Randomization Method with the Size 4, will be used. Considering the Time of Entry into the Study and Considering that A is (Intervention Group) and B is (Placebo Group), A Part of the Random Allocation will be in the Following Order: Randomization will be done with SAS software version 9. Seed: 253569775886591 Block sizes: 4 Actual list length: 86 block identifier, block size, sequence within block, treatment • 1, 4, 1, Group B • 1, 4, 2, Group A • 1, 4, 3, Group B • 1, 4, 4, Group A • 2, 4, 1, Group B • 2, 4, 2, Group A • 2, 4, 3, Group A Assignment of Groups will be performed through Closed Envelopes. The Resident Implementing the Project will register the Participants and the Allocation Sequence will be done by A Statistician through the Relevant Softwares.
Blinding (investigator's opinion)
Double blinded
Blinding description
Researcher and participants are blind in this study (double-blind). The Researcher does not know which participant is in the intervention or control group. The participant does not know whether he/ she is in the intervention or control group. Both groups will receive sachet with the same shape and color with different contents. Intervention and control sachets will be noted as A and B by a pharmacist unaware about the research and will be given to the researcher.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Guilan University of Medical Sciences
Street address
In front of 17 Shahrivar Hospital, Siadati Ave, Namjou Blvd
City
Rasht
Province
Guilan
Postal code
4144654379
Approval date
2022-02-23, 1400/12/04
Ethics committee reference number
IR.GUMS.REC.1400.595

Health conditions studied

1

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

Primary outcomes

1

Description
Blood glucose level
Timepoint
Blood glucose level measurement at the beginning of the intervention (Before the start of the intervention) and 12 weeks after the start of synbiotic and/or placebo usage
Method of measurement
BT-3000 chemistry analyzer

2

Description
Glycated hemoglobin (HbA1c)
Timepoint
Glycated hemoglobin (HbA1c) measurement at the beginning of the intervention (Before the start of the intervention) and 12 weeks after the start of synbiotic and/or placebo usage
Method of measurement
BT-3000 chemistry analyzer

Secondary outcomes

1

Description
Hypoglycemia incidence
Timepoint
Determining the hypoglycemia incidence at any time of performing the intervention
Method of measurement
Glucometer

2

Description
Incidence of Diabetic Ketoacidosis (DKA)
Timepoint
Determining the Incidence of Diabetic Ketoacidosis (DKA) at any time of performing the intervention
Method of measurement
Ketone bodies level and Arterial Blood Gas

3

Description
The need for injectable insulin
Timepoint
Determining the need for injectable insulin at any time of performing the intervention
Method of measurement
Based on the patient's blood sugar using a glucometer

Intervention groups

1

Description
Intervention group: Synbiotic (Kidilact sachet of Zist-Takhmir company with the power of 10^9 CFU, containing Lactobacillus rhamnosus, Lactobacillus reuteri, Lactobacillus acidophilus, Lactobacillus bulgaricus, Lactobacillus casei, Bifidobacterium infantis, Bifidobacterium breve, Bifidobacterium bifidum, Bifidobacterium lactis, Sterptococcus thermophilus Suchets and Fructooligosaccharide) is given to the intervention's group participants in same pre-weighed powder form foil packages. Everyday, participants mix one sachet weighing 1 gram with 250ml water and drink it 15-20 mins before the evening meal. For the first 2 weeks, participants are asked to take only half-dose to reduce gastrointestinal side effects, after which they take the full-dose for the remaining 10 weeks.
Category
Treatment - Other

2

Description
Control group: Placebo (Product of Zist-Takhmir company, Containing Lactose monohydrate 80 Mesh, Inulin, Talc, Magnesium stearate, Colloidal silicon dioxide, Sucralose, Corn flour and Xanthan gum) is given to the control's group participants in same pre-weighed powder form foil packages. Everyday, participants mix one sachet weighing 1 gram with 250ml water and drink it 15-20 mins before the evening meal. For the first 2 weeks, participants are asked to take only half-dose to reduce gastrointestinal side effects, after which they take the full-dose for the remaining 10 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrine Clinic of 17 Shahrivar Hospital
Full name of responsible person
Setila Dalili
Street address
17 Shahrivar Educational, Therapeutic and Research Center, South of the City Park, Siadati Ave, Namjou Blvd
City
Rasht
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Guilan
Postal code
4144654379
Phone
+98 13 3336 9019
Email
17shahrivar@gums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
MohammadReza Naghipour
Street address
In front of 17 Shahrivar Hospital, Siadati Ave, Namjou Blvd
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Email
research@gums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
The Vice-Chancellor of Research at Guilan 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
Rasht University of Medical Sciences

Full name of responsible person
Afagh Hassanzadeh Rad

Position
Researcher

Latest degree
Ph.D.

Other areas of specialty/work
Pediatrics

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17 Shahrivar Educational, Therapeutic and Research Center, South of the City Park, Siadati Ave, Namjou Blvd

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Setila Dalili

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Regarding to the ethical considerations

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available