

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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		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.	
Public title	Effect of synbiotic on diabetes control	Placebo	Used
Purpose	Treatment	Assignment	Parallel
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 Blood Sugar (FBS) $\geq$ 126 mg/dl Glucose, 2 hour Post Prandial (2hpp) $\geq$ 200 mg/dl Glycated Hemoglobin (HbA1c) $\geq$ 6.5% Blood Sugar (BS) $\geq$ 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	Other design features	
Age	From 4 years old to 18 years old	Secondary Ids	empty
Gender	Both	Ethics committees	
Phase	3	1	
Groups that have been masked	- Participant - Investigator - Outcome assessor	Ethics committee	
Sample size	Target sample size: 86	Name of ethics committee	Ethics Committee of Guilan University of Medical Sciences
Randomization (investigator's opinion)	Randomized	Street address	In front of 17 Shahrivar Hospital, Siadati Ave, Namjou Blvd
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.	City	Rasht
Blinding (investigator's opinion)	Double blinded	Province	Guilan
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	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

Province

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

City

Rasht

Province

Guilan

Postal code

4144654379

Phone

+98 13 3333 5820

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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afaghrad@gums.ac.ir

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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setiladalili1346@yahoo.com

Person responsible for updating data

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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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