Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 2026

The effect of combination therapy with insulin and synbiotic on platelet indices in children with type 1 diabetes

Protocol summary

Study aim
To determine the effect of combination therapy with insulin and synbiotic on platelet indices in children with type 1 diabetes

Design
Clinical trial with control group, parallel groups, double-blind, randomized, phase 3 on 76 patients. SAS software version 9 will be used for randomization.

Settings and conduct
In this randomized, double-blind, clinical trial (blinding for participants and the researcher) we investigate the effect of KidiLact supplement (produced by Zist-Takhmir Company - Iran) on platelet indices in 4-18 years-old children with type 1 diabetes referring to endocrinology clinic of 17 Shahrivar Hospital in Rasht. In this study, for 12 weeks, in addition to the main treatment (injectable insulin), the intervention group is given 1 sachet of synbiotic and the control group is given 1 sachet of placebo, daily. At the beginning and the end of the intervention, 5cc blood samples are taken from the participants to evaluate and compare biochemical factors.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children 4-18 years; Being treated with injectable insulin; Having type 1 diabetes Non-inclusion criteria: Taking antibiotics, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), immunosuppressants during the last month; Taking products containing probiotics and synbiotics in the last month; Metabolic disease; Gastrointestinal disease; Cardiovascular disease (CVD); Renal disease

Intervention groups
Daily, the intervention group takes 1 sachet of KidiLact supplement (product of Zist-Takhmir Company - Iran) for 12 weeks. The control group also takes 1 sachet of placebo (product of Zist-Takhmir Company - Iran) daily for 12 weeks.

Main outcome variables
Blood Platelet Count (PLT); Platelet Percentage (PCT); Mean Platelet Volume (MPV); Platelet Distribution Width (PDW)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220313054269N1**
Registration date: **2022-05-24, 1401/03/03**
Registration timing: **prospective**

Last update: **2022-05-24, 1401/03/03**
Update count: **0**

Registration date
2022-05-24, 1401/03/03

Registrant information

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Seyed Jafar Aldaghi

Name of organization / entity
Science and Research Branch of Islamic Azad University

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-28, 1401/03/07

Expected recruitment end date
2022-08-19, 1401/05/28

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of combination therapy with insulin and synbiotic on platelet indices in children with type 1 diabetes

Public title
Effect of synbiotic in treatment of diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Girls and Boys 4-18 Years Being Treated with Injectable Insulin Fasting Blood Sugar (FBS) ≥ 126 mg/dl Glucose, 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:
Taking antibiotics, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), immunosuppressants during the last month Taking products containing probiotics and synbiotics in the last month Metabolic disease Gastrointestinal disease Cardiovascular disease (CVD) Renal disease
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: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
To randomize the treatment between two groups, Permuted Block Randomization Method with the Size 4, will be used. Considering the time of patients entry into the study and that A is (Intervention group) and B is (Control group), A Part of the Random Allocation will be as follows: Randomization is done with SAS software version 9. Seed: 253569775886591 Block sizes: 4 Actual list length: 76 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 B • 2, 4, 4, Group A Groups assignment will be performed by the closed envelopes. The researcher registers the participants and the statistician determines the allocation sequence using the relevant softwares.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this double-blind, randomized, clinical trial, blinding will be performed for the researcher (outcome assessor) and the participants. The researcher (outcome assessor) doesn't know which participant is in the intervention or control group and the participants don't know which group they are in.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Islamic Azad University, Science and Research Branch
Street address
Science and Research Branch, Daneshgah Square, Simon Bulivar Blvd, Ashrafi Esfahani Expy
City
Tehran
Province
Tehran
Postal code
1477893855
Approval date
2021-11-02, 1400/08/11
Ethics committee reference number
IR.IAU.SRB.REC.1400.175

Health conditions studied

1

Description of health condition studied
Type 1 diabetes
ICD-10 code
E10.9
ICD-10 code description
Type 1 diabetes mellitus without complications

Primary outcomes

1

Description
Blood Platelet Count (PLT)
Timepoint
Blood Platelet counting 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
Sysmex XS800 hematology analyzer

2

Description
Platelet Percentage (PCT)
Timepoint
Platelet Percentage calculating 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
Sysmex XS800 hematology analyzer

3

Description
Mean Platelet Volume (MPV)
Timepoint
Mean Platelet Volume calculating 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
Sysmex XS800 hematology analyzer

4

Description
Platelet Distribution Width (PDW)
Timepoint
Platelet Distribution Width calculating 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
Sysmex XS800 hematology analyzer

Secondary outcomes

empty

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 the same 1 gram powder form sachets. Everyday, participants mix one sachet weighing 1 gram with 250ml water and drink it 15-20 mins before the evening meal.
Category
Treatment - Drugs

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 intervention's group participants in the same 1 gram powder form sachets. Everyday, participants mix one sachet weighing 1 gram with 250ml water and drink it 15-20 mins before the evening meal.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice-Chancellor for Research & Technology, Islamic Azad

University, Science and Research Branch

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
Islamic Azad University, Science and Research Branch

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Position
Assistant Professor

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Other areas of specialty/work
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Other areas of specialty/work
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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
Confidentiality of patients information

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