

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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-Takhmīr 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-Takhmīr Company - Iran) for 12 weeks. The control group also takes 1 sachet of placebo (product of Zist-Takhmīr 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

Name

Seyed Jafar Aldaghi

Name of organization / entity

Science and Research Branch of Islamic Azad University

Country

Iran (Islamic Republic of)

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+98 938 561 1676

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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) $\geq 6.5\%$ 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

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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

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

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Sponsors / Funding sources

1

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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

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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