

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Evaluation of the effect of probiotic supplementation *Saccharomyces Boulardii*(babyeast) compared to placebo on HA1c level in patients with type 1 diabetes

Protocol summary

Study aim

The use of *Saccharomyces Boulardii* (babyeast) probiotic in patients with type 1 diabetes to control glucose.

Design

This study is a randomized, placebo-controlled, double-blind, single-center clinical trial.

Settings and conduct

The current study was a double-blind randomized controlled clinical trial and was conducted on a population of 2 to 18 years old with type 1 diabetes who referred to Tehran Mofid hospital clinic in 1400. The samples were randomly divided into two groups receiving probiotics and placebo. Researchers and patients were blinded to the contents of the sachets.

Participants/Inclusion and exclusion criteria

The research community includes; The population of 2 to 18 years old with type 1 diabetes referred to Mofid hospital clinic in 1400 for routine care. History of hospitalization for medical or psychiatric reasons and unwillingness to continue cooperation are taken into account in order to withdraw patients from the plan.

Intervention groups

Intervention group: Babyeast sachets contain 250 mg of lyophilized *Saccharomyces boulardii* yeast. 90 days after the start of the study, the subjects will go to the clinic and the necessary drugs will be given for the next 90 days, and the same data will be collected again on the 180th day of the study. Control group: Placebo is also made by Knowledge Enterprise biologyfermentation company similar to probiotic drug in Babyeast sachets containing 250 mg and provided to the researcher.

Main outcome variables

HbA1c; FBS; Average blood glucose 2 hours after a meal; the total amount of insulin received daily; triglycerides; HDL; Average FBS recorded by the patient; LDL and Cholesterol

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230225057530N1**

Registration date: **2023-07-19, 1402/04/28**

Registration timing: **retrospective**

Last update: **2023-07-19, 1402/04/28**

Update count: **0**

Registration date

2023-07-19, 1402/04/28

Registrant information

Name

Maryam Sahraei ardakani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-20, 1401/10/30

Expected recruitment end date

2023-03-19, 1401/12/28

Actual recruitment start date

2023-01-20, 1401/10/30

Actual recruitment end date

2023-03-19, 1401/12/28

Trial completion date

empty

Scientific title

Evaluation of the effect of probiotic supplementation Saccharomyces Boulardii(babyeast) compared to placebo on HA1c level in patients with type 1 diabetes

Public title

Evaluation of the effect of probiotics in patients with type 1 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Type 1 diabetes Diagnosed 18 months before entering the study Refer to Mofid hospital clinic for routine care in 1400

Exclusion criteria:

Patients do not have a history of hospitalization for medical or psychiatric reasons in the last 12 months. It is not possible to access by phone.

Age

From **2 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling has been done by census method and.Patients are randomly assigned to one of the two placebo and probiotic groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Babyeast sachets contain 250 mg of Saccharomyces boulardi lyophilized yeast.Placebo is also made by Knowledge enterprise biology fermentation company similar to probiotic drug and provided 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 Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Arabi Ave, Student Blvd, Valenjak, Tehran

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Province

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Postal code

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Approval date

2023-05-02, 1402/02/12

Ethics committee reference number

IR.SBMU.MSP.REC.1402.026

2

Ethics committee

Name of ethics committee

Ethics committee of Endocrine and Metabolism Research Institute, Tehran University of Medical Scienc

Street address

Endocrinology and Metabolism Research Institute, next to Dr. Shariati Hospital, Jalal Al Ahmad Highway

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1411713119

Approval date

2023-02-15, 1401/11/26

Ethics committee reference number

IR.TUMS.EMRI.REC.1401.158

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

Age Of The Patient

Timepoint

At The Beginning Of The Study

Method of measurement

Questionnaire-Clinical File

2

Description

Gender Of The Patient

Timepoint

At The Beginning Of The Study

Method of measurement

Questionnaire-Clinical File

3

Description

Patient Weight

Timepoint

At The Beginning Of The Study

Method of measurement

Scales

4

Description

Height Of The Patient

Timepoint

At The Beginning Of The Study

Method of measurement

Meter

5

Description

The Stage Of Maturation Of The Patient

Timepoint

At The Beginning Of The Study

Method of measurement

Questionnaire-Clinical File

6

Description

Patient Activity Level

Timepoint

At The Beginning Of The Study

Method of measurement

Questionnaire-Clinical File

7

Description

Duration Of Diagnosis Of Diabetes

Timepoint

At The Beginning Of The Study

Method of measurement

Questionnaire-Clinical File

8

Description

Type Of Insulin Used By The Patient

Timepoint

At The Beginning Of The Study

Method of measurement

Questionnaire-Clinical File

9

Description

The Total Amount Of Insulin Received Daily

Timepoint

At the beginning of the study, day 90 and day 180 in patients

Method of measurement

Questionnaire-Clinical File

10

Description

Fasting Blood Sugar

Timepoint

At the beginning of the study, day 90 and day 180 in patients

Method of measurement

Paraclinic - Laboratory

11

Description

Average Fasting Sugars

Timepoint

At the beginning of the study, day 90 and day 180 in patients

Method of measurement

Paraclinic - Laboratory

12

Description

Average Sugars 2 Hours After a Meal

Timepoint

At the beginning of the study, day 90 and day 180 in patients

Method of measurement

Paraclinic - Laboratory

13

Description

HbA1C

Timepoint

At the beginning of the study, day 90 and day 180 in patients

Method of measurement

Paraclinic - Laboratory

14

Description

HDL

Timepoint

At the beginning of the study, day 90 and day 180 in patients

Method of measurement

Paraclinic - Laboratory

15

Description

LDL

Timepoint

At the beginning of the study, day 90 and day 180 in patients

Method of measurement

Paraclinic - Laboratory

16**Description**

Cholesterol

Timepoint

At the beginning of the study, day 90 and day 180 in patients

Method of measurement

Paraclinic - Laboratory

17**Description**

Triglyceride

Timepoint

At the beginning of the study, day 90 and day 180 in patients

Method of measurement

Paraclinic - Laboratory

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Babyeast sachets contain 250 mg of Saccharomyces boulardi lyophilized yeast. This product does not contain gluten or sweeteners. Each person is given 180 sachets for 6 months. 90 days after the start of the study, the subjects went to the clinic, and at that time, the daily insulin consumption, the average fasting and 2-hour post-meal sugars, and HbA1c will be collected, and the drugs needed for the next 90 days will be given, and again on the 180th day of the study, the above data will be collected. is collected.

Category

Treatment - Drugs

2**Description**

Control group: Placebo is also made by Knowledge Enterprise biologyfermentation company similar to probiotic drug in Babyeast sachets containing 250 mg and provided to the researcher

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mofid Children's Hospital

Full name of responsible person

Marjan Shakiba

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Mofid Children's Hospital, Dr. Shariati Ave

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

1

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

Sponsor**Name of organization / entity**

Endocrine and Metabolism Research Institute, Tehran
University of Medical Sciences

Full name of responsible person

Neda Mehrdad

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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

Endocrine and Metabolism Research Institute, Tehran
University of Medical Sciences

Proportion provided by this source

99

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Sahraei ardakani

Position

Subspecialty Assistant

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data can potentially be shared after de-identifying individuals

When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
The data will be available to researchers working in academic and scientific institutions and people working in industry
Under which criteria data/document could be used
Unlimited
From where data/document is obtainable
Dr. Maryam Sahrai Ardakani. 09393131367.
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What processes are involved for a request to access data/document
Unlimited
Comments