Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 boulardi 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

Country
Iran (Islamic Republic of)

Phone
+98 21 2222 7021

Email address
m.sahraei67@yahoo.com

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
City
Tehran
Province
Tehran
Postal code
1985717443
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
City
Tehran
Province
Tehran
Postal code
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
Street address
Mofid Children's Hospital, Dr. Shariati Ave
City
Tehran
Province
Tehran
Postal code
15468-15514
Phone
+98 21 2222 7021
Email
info-mch@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Building No. 2, Shahid Arabi Ave, Yemen Ave, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9780
Email
info@sbmu.ac.ir
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

2

Sponsor

Name of organization / entity
Endocrine and Metabolism Research Institute, Tehran University of Medical Sciences

Full name of responsible person
Neda Mehrdad

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

City
Tehran

Province
Tehran

Postal code
1411713119

Phone
+98 21 8863 1298

Email
emrc@tums.ac.ir

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

Street address
Mofid hospital, Dr shariatee Ave

City
Tehran

Province
Tehran

Postal code
1546815514

Phone
+98 21 2222 7021

Fax

Email
m.sahraei67@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Marjan Shakiba

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

Street address
Mofid Children's Hospital, Dr. Shariati Ave

City
Tehran

Province
Tehran

Postal code
1546815514

Phone
+98 21 2222 7021

Email
shakibamarjan@yahoo.com

Person responsible for updating data

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

Street address
Dr shariatee Ave, Mofid hospital

City
Tehran

Province
Tehran

Postal code
1546815514

Phone
+98 21 2222 7021

Fax

Email
m.sahraei67@yahoo.com

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. m.sahraei67@yahoo.com.

What processes are involved for a request to access data/document

Unlimited

Comments