Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of efficacy of oral Probiotic in glycemic control and duration of honeymoon period in children affected by Diabetes mellitus -type 1

Protocol summary

Study aim
The purpose of this randomized controlled clinical trial is to study the effect of probiotics on glycemic control and duration of honeymoon period in newly diagnosed type 1 diabetic children. The hypothesis is that probiotics may increase the duration of honeymoon period or can induce better glycemic control due to their immunomodulatory effects on residual beta cells.

Design
parallel group, double blind, randomized controlled trail.

Settings and conduct
Study recruitment will be from inpatients and outpatient clinic of Akbar Hospital in Mashhad university of medical sciences

Participants/Inclusion and exclusion criteria
At least one hundred thirty Children aged 6-18 years old with newly diagnosed diabetes type one participate in the trial. Diagnosis of type one DM is made as defined by International Society for Pediatric and Adolescent Diabetes (ISPAD) criteria. Study recruitment will be from inpatients and outpatient clinic of Akbar Hospital in Mashhad university of medical sciences during March 2022 to March 2023. Patients who meet the inclusion criteria will enter the study.

Intervention groups
The intervention consists of administration of probiotics or placebo to newly diagnosed children with type 1 diabetes for a six month period. The placebo is quite similar in taste and appearance to the active product. Products are manufactured in the form of capsules and are supplied free of charge by ZIST TAKHMIR company, Iran. This company has no role in study concept and conduct and the analysis and interpretation of data. Participants are followed at 3 month intervals for one year. At each visit anthropometrical data, glycemic control and total dose of insulin required to keep the optimal glycemic control is evaluated and registered.

Main outcome variables
The main variable of the study are fasting c-peptide levels and HbA1c levels.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200117046164N3**
Registration date: **2022-03-13, 1400/12/22**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-13, 1400/12/22**
Update count: **0**

Registration date
2022-03-13, 1400/12/22

Registrant information

Name
Nasrin Moazzen

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3840 0000

Email address
moazzenn@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-24, 1400/12/05

Expected recruitment end date
2023-02-24, 1401/12/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigation of efficacy of oral Probiotic in glycemic control and duration of honeymoon period in children affected by Diabetes mellitus -type 1

Public title
oral Probiotic in Diabetes mellitus -type 1
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Newly diagnosed children with type1diabetes mellitus aged between 6-18 years old.
Exclusion criteria:
Presence of comorbid conditions like significant cardiac, hepatic or renal disease Presence of immunodeficiency Allergy to probiotics Patients not willing to continue participating in the study
Age
From **6 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: **130**
Randomization (investigator's opinion)
Randomized
Randomization description
A simple randomization will be carried out on an individual basis by Rand List software. The allocation will be seated by an independent monitor and will not be broken until the end of the study. The patients are randomly assigned to the intervention or control group. They are allocated in a 1:1 ratio to each group.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The researchers are blinded to group assignments. After preparation of probiotic capsule, each of them will have a randomized code; then clinicians blindly administer them to patients in two groups of case and control. After data gathering, they will be analyzed blindly. All follow up data are collected by two researchers who are blinded to group assignments. The researchers who generate the randomization sequence are not involved in the treatment or future evaluation of the participants.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of mashhad university of medical sciences
Street address
Knowledge and Health City – In the end of Shahid Fakouri Blvd (In front of Fakouri 94) – Mashhad - Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
91778-99191
Approval date
2022-01-17, 1400/10/27
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1400.800

Health conditions studied

1

Description of health condition studied
diabetes mellitus type 1
ICD-10 code
E10
ICD-10 code description
Type 1 diabetes mellitus

Primary outcomes

1

Description
fasting c-peptide levels
Timepoint
before intervention and then every 3 months up to one year
Method of measurement
laboratory

2

Description
HbA1c levels.
Timepoint
before intervention and then every 3 months up to one year
Method of measurement
laboratory

Secondary outcomes

1

Description
Anthropometric parameters
Timepoint
before intervention and then every 3 months up to one year
Method of measurement
digital scale

2

Description
Insulin requirements
Timepoint
before intervention and then every 3 months up to one year
Method of measurement
asking patient and based on prescribed insulin for glycemic control

Intervention groups

1

Description
Intervention group: The intervention consists of administration of probiotics to newly diagnosed children with type 1 diabetes aged 6-18 years for a six month period. Products are manufactured in the form of capsules and are supplied free of charge by ZIST TAKHMIR company, Iran. it contains these strains: Lactobacillus rhamnosus• Lactobacillus casei• Lactobacillus bulgaricus• Lactobacillus acidophilus• Bifidobacterium breve• Bifidobacterium longum • Streptococcus thermophilus10^9CFU .Other ingredients: Fructooligosaccharides (FOS) as prebiotic,This product is gluten-free.
Category
Treatment - Drugs

2

Description
Control group: The intervention consists of administration of placebo to newly diagnosed children with type 1 diabetes aged 6-18 years for a six month period. Products are manufactured in the form of capsules and are supplied free of charge by ZIST TAKHMIR company, Iran. it contains Other ingredients of above mentioned product Fructooligosaccharides (FOS) as prebiotic,This product is gluten-free and without probiotic.The placebo is quite similar in taste and appearance to the active product.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology Department of Akbar children's medical center, Mashhad, Iran
Full name of responsible person
nosrat ghaemi
Street address
infront of No.14 Shahid Kaveh, Kaveh Blvd, Mashhad, Iran
City
Mashhad
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Razavi Khorasan
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9177897157
Phone
+98 51 3871 3801
Email
moazzenn@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayour Mobarhan
Street address
Daneshgah Blvd, Mashhad university of medical sciences, Mashhad, Iran
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Postal code
9138813944
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+98 51 3841 1538
Email
vcresraech@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Nasrin Moazzen
Position
assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Immunology
Street address
Knowledge and Health City – In the end of Shahid Fakouri Blvd (In front of Fakouri 94) – Mashhad - Iran
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available