Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the Effect of Synbiotic Supplements on Hyperglycemia and Insulin Resistance in Patients with Type 2 Diabetes: A Randomized Double-blinded, Clinical Trial

Protocol summary

Study aim
Evaluating the Effect of Synbiotic Supplements on Hyperglycemia and Insulin Resistance in Patients with Type 2 Diabetes

Design
clinical trial with parallel groups; with two intervention groups and one control group, double-blind, randomized, on 194 patients. Random allocation software was used for randomization.

Settings and conduct
The effectiveness of synbiotic supplement on hyperglycemia and insulin resistance in patients with type 2 diabetes is investigated in the clinics of Shahid Rajaei Hospital in Tankabon and also Imam Sajad in Ramsar. Patients are divided into two groups of 97 synbiotics and control, and each group receives one tablet twice a day for 3 months. Patients, prescribers, and data analysts will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients in the age group of 30 to 75 years with type 2 diabetes who are diagnosed based on the latest American Diabetes Association(ADA) guidelines. Exclusion criteria: Pregnant and lactating women Patients receiving hormone therapy, including estrogen and progesterone. Hypothyroidism Patients with kidney disease that have a creatinine level more than two times the upper normal limit. Consumption of any Probiotic, Synbiotic products and Antibiotics in the last three months. Alcohol consumption

Intervention groups
97 Patients are in the synbiotic Supplements Intervention Group. Patients will receive the supplements twice daily for three months.

Main outcome variables
blood sugar ; Insulin resistance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230212057393N2**
Registration date: **2023-04-18, 1402/01/29**
Registration timing: **prospective**

Last update: **2023-04-18, 1402/01/29**
Update count: **0**

Registration date
2023-04-18, 1402/01/29

Registrant information

Name
Fahimeh Naderi-Behdani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 5523 1912

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fahime.naderi90@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-05, 1402/02/15

Expected recruitment end date
2023-08-06, 1402/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the Effect of Synbiotic Supplements on Hyperglycemia and Insulin Resistance in Patients with Type 2 Diabetes: A Randomized Double-blinded, Clinical Trial

Public title
Evaluating the Effect of Synbiotic Supplements on type 2 Diabetes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients in the age group of 30 to 75 years with type 2 diabetes who are diagnosed based on the latest American Diabetes Association(ADA) guidelines.
Exclusion criteria:
Pregnant and lactating women Patients receiving hormone therapy, including estrogen and progesterone. Hypothyroidism Patients with kidney disease that have a creatinine level more than two times the upper normal limit. Consumption of any Probiotic, Synbiotic products and Antibiotics in the last three months. Alcohol consumption

Age
From **30 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **194**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of allocating samples into two groups will be based on block classification. The blocking process will be done using random allocation software. This software will generate blocks, and samples will be studied based on the principles of random numbers generated. Based on the above method, the studies will be divided into two synbiotic and control groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients, physicians, and statisticians will not know the intervention distribution. Synbiotic supplements and placebo capsules are entirely similar in terms of appearance, shape, smell, and color and are distinguished from each other only by the A and B codes. Only the data safety and monitoring committee knows its contents and codes.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ramsar International Campus
Street address
Enghelab Sq, Emam Sajad Hospital Ramsar , Mazandaran
City
Ramsar
Province
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Postal code
4691714141

Approval date
2023-02-19, 1401/11/30

Ethics committee reference number
IR.MAZUMS.RIB.REC.1401.104

Health conditions studied

1

Description of health condition studied
Diabetes mellitus

ICD-10 code
E14.9

ICD-10 code description
Diabetes mellitus without complications

Primary outcomes

1

Description
hyperglycemia

Timepoint
In the beginning, and after three months

Method of measurement
Test kit for measuring blood sugar

2

Description
Insulin Resistance

Timepoint
In the beginning, and after three months

Method of measurement
ELISA Insulin Kit

Secondary outcomes

1

Description
Lipid Profiles
Timepoint
At the Baseline and three months after entering the trial
Method of measurement
Blood test

2

Description
Body Mass Index
Timepoint
At the Baseline and three months after entering the Trial
Method of measurement
Scale and Tape Measure

3

Description
Systolic and Diastolic Blood Pressure
Timepoint
At the baseline and three months after entering the Trial
Method of measurement
Mercury Sphygmomanometer

4

Description
measure psychological disorder
Timepoint
At the baseline and three months after entering the trial
Method of measurement
The General Health Questionnaire – 28

5

Description
Appetite assessment
Timepoint
At the Baseline and every month after entering the trial
Method of measurement
Question by the research team by phone

6

Description
Evaluating the stool condition of patients
Timepoint
At the Baseline and every month after entering the trial
Method of measurement
Question by the research team by phone

Intervention groups

1

Description
97 Patients are in the synbiotic Supplements(Familact, zisttakhmir Company) Intervention Group. Patients will receive The supplements twice daily for three months.
Category
Treatment - Drugs

2

Description
ninety-seven patients are in the control group. Patients will receive placebo with the same shape, color, and smell as our intervention supplements, twice a day for 3 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Sajad Ramsar Hospital
Full name of responsible person
Fahimeh Naderi Behdani
Street address
Enghelab Sq, Emam Sajad Hospital Ramsar, Ramsar City
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Mahsa Narenji
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Enghelab Sq, Emam Sajad Hospital, Ramsar City
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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
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Taha Ghasemi
Position
medical student
Latest degree
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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
there is no more 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