

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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

##### Email address

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**

Mazandaran

**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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#### **Phone**

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#### **Email**

fahime.naderi90@gmail.com

## 2

### **Recruitment center**

#### **Name of recruitment center**

Shahid Rajaei Tonekabon Hospital Clinics

#### **Full name of responsible person**

Fahimeh Naderi Behdani

#### **Street address**

Emam Sajad Hospital, Enghelab Sq, Ramsar City

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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

**Street address**

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**

Bachelor

**Other areas of specialty/work**

General Practitioner

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**Email**

mr.taha.ghasemi@gmail.com

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

Mazandaran University of Medical Sciences

**Full name of responsible person**

Fahimeh Naderi Behdani

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Clinical Pharmacy

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fahime.naderi90@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

MohammadTaha Ghasemi

**Position**

medical student

**Latest degree**

Bachelor

**Other areas of specialty/work**

General Practitioner

**Street address**

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**City**

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**Phone**

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**Email**

mr.taha.ghasemi@gmail.com

**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