

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of symbiotic supplement containing *Bacillus coagulans* and fructo oligosaccharide on glycemic index , cardiovascular risk factors and and systemic inflammation in patients with type 2 diabetes

Protocol summary

Study aim

The effects of symbiotic supplementation of *Bacillus coagulans* and fructo oligosaccharide on glucose metabolism, insulin concentration, insulin resistance, lipid profiles and systemic inflammation in type 2 diabetic patients

Design

The present study will be conducted as a phase 3, randomized double-blind placebo controlled trial on 40 type 2 diabetics patients allocated in 2 parallel groups each consisted of 20 patients who will receive symbiotic or placebo. From the beginning of the study, A and B codes are available to researchers to recruit the patients using simple Randomization.

Settings and conduct

The study will perform at Imam Hossein Hospital. Information on demographic data and 24 hours recall will be collected. Patients will be blinded about the intervention type and will be randomized to either the placebo or intervention group at the beginning of study for 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria The willingness to participate • Age from 30 to 70 years • Body mass index ≤ 35 kg / m² • Having type 2 diabetes • Pregnancy and lactation • Not getting thyroid gland disorders • Lack of kidney and inflammatory disease • Lack of weight loss regimens 6 months before the start of the study • No use of glucocorticoids and non-steroidal anti-inflammatory drugs • Do not use of insulin Exclusion criteria • Complications associated with supplementation • Not using regular supplement • Consume less than 80% of supplements in three months

Intervention groups

Patients in the intervention group will receive 1 sachet containing symbiotic in addition to routine medications. While the control group will receive 1 placebo sachet

which will be indistinguishable from symbiotic sachets in taste and appearance.

Main outcome variables

Fasting blood sugar; Triglyceride; Low-density lipoprotein; High-density lipoprotein; Insulin level; High sensitive C reactive protein level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190103042220N1**

Registration date: **2019-01-07, 1397/10/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-07, 1397/10/17**

Update count: **0**

Registration date

2019-01-07, 1397/10/17

Registrant information

Name

aynaz velayaty

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2235 7483

Email address

avelaty@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-05, 1397/03/15

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of symbiotic supplement containing Bacillus coagulans and fructo oligosaccharide on glycemic index , cardiovascular risk factors and and systemic inflammation in patients with type 2 diabetes

Public title
The effects of symbiotic supplement on complications of type 2 diabetes

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to cooperate and complete informed consent form • Patients aged 30-70 years • Body mass index $\leq 35 \text{ kg / m}^2$ • haveType 2 diabetes • No history of alcohol or alcohol less than 10 grams Per day in women and less than 20 grams per day in men • no pregnancy and lactation • no thyroid gland disorders • no kidney and inflammatory disease • failure to follow weight loss regimens 6 months before the start of the study • no use Slimming drugs (Orlites, Slim Lists) and fat burners, fiber powder • Non-use of glucocorticoids and non-steroidal anti-inflammatory drugs • no use of insulin
Exclusion criteria:
•show complications associated with supplementation• No regular use of supplement• Consume less than 80% of supplements in three months

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
in this study simple randomization will used for sample selection with using table of random numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
in this study participants and researchers will not aware of the type of assigned innervation for each patients. Symbiotic or placebo are marked by A or B codes and patients will receive one of them randomly.

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

No. 7, Hafezi Ave., Farahzadi Blvd., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2018-10-20, 1397/07/28

Ethics committee reference number

IR.SBMU.nnftri.Rec.1397.230

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11.9

ICD-10 code description

Type 2 diabetes mellitus without complications

Primary outcomes

1

Description

Changes in fasting blood sugare

Timepoint

At the baseline of intervention and at the end of study.

Method of measurement

Enzymatic methods using kit

2

Description

Triglyceird level

Timepoint

At the baseline of intervention and at the end of study.

Method of measurement

Enzymatic methods using kit

3

Description

Low-density lipoprotein

Timepoint

At the baseline of intervention and at the end of study.

Method of measurement

Enzymatic methods using kit

4

Description

High-density lipoprotein

Timepoint

At the baseline of intervention and at the end of study.

Method of measurement

Enzymatic methods using kit

5

Description

Serum insulin level

Timepoint

At the baseline of intervention and at the end of study.

Method of measurement

Enzymatic methods using kit

6

Description

High-sensitive C-reactive protein

Timepoint

At the baseline of intervention and at the end of study.

Method of measurement

Enzymatic methods using kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group will receive 1 sachets contains symbiotic every day for 12 weeks

Category

Treatment - Other

2

Description

Control group: Control group will receive 1 placebo every day for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Imam hossein Hapital

Full name of responsible person

Golbon Sohrab

Street address

۲۳:۰۹۰۵.۰۱.۱۹] پگاه رفیعی, No. 7, Hafezi Ave., Farahzadi Blvd., Qods Town,

City

Tehran

Province

Tehran

Postal code

235680052

Phone

+98 21 7343 0335

Email

info@ehmc.ir

Web page address

<http://www.ehmc.ir/>

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Morteza Abdollahi

Street address

No. 7, Hafezi Ave., Farahzadi Blvd., Qods Town,

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7483

Fax

+98 21 2236 0660

Email

info@nnftri.ac.ir

Web page address

<http://nnftri.ac.ir/en/home/>

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

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**

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Golbon Sohrab

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

No. 7, Hafezi Ave., Farahzadi Blvd., Qods Town,

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7483

Email

golbonsohrab@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Golbon Sohrab

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

No. 7, Hafezi Ave., Farahzadi Blvd., Qods Town,

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7483

Fax

+98 21 2236 0660

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Aynaz Velayaty

Position

students

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

No. 7, Hafezi Ave., Farahzadi Blvd., Qods Town,

City

tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7483

Fax

+98 21 2236 0660

Email

avelayaty@gmail.com

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