Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 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 2diabetics 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 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 participant • 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 Exclision 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 1sachet containing symbiotic in addition to routine medications. While the control group will receive 1 placebo sachet which will be indistinguishable from symbiotic sachetes in taste and appearance.

Main outcome variables

Fasting blood surge;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

avelayaty@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 informed consent form • Patients aged 30-70 years • Body mass index ≤ 35 kg / m2 • 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
پگاه رفیعی, ۲۳:۰۹ ۰۵.۰۱.۱۹] No. 7, Hafezi Ave., Farahzadi Blvd., Qods Town,
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Tehran
Province
Tehran
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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,
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Fax
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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

Academic

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

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Person responsible for updating data

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students

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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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