Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of multi-strain synbiotic supplementation on insulin resistance, liver enzymes, inflammatory, and anthropometric indices in diabetic, obese, and overweight patients with non-alcoholic fatty liver disease

Protocol summary

Study aim
Determining the effect of multistrain synbiotic supplementation on insulin resistance, liver enzyme, inflammatory and anthropometric indices in overweight and obese adults with co-morbidities of diabetes and fatty liver

Design
This study is a clinical control trial, parallel groups, triple-blind, randomized, phase 3, on 40 participants (20 people in the intervention group and 20 people in the control group).

Settings and conduct
Patients with fatty liver and diabetes referred to Motahari Clinic in Shiraz after obtaining informed consent and evaluating and confirming the conditions for entering the study, blood samples will be taken from and background information will be recorded. Then, according to the randomization sequence, they will be divided into one of the intervention or control groups and receive synbiotic supplement or placebo along with diet for 12 weeks. After the end of the intervention period, the patients return to the clinic for final tests. The research team and participants were blinded regarding the allocation of subjects to control or intervention groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having fatty liver (grade 2 or 3). Having diabetes and prediabetes (fasting blood sugar above 100). Being overweight or obese (BMI greater than 25) Exclusion criteria: Taking antibiotics or probiotic supplements in the 3 months before the study. Pregnancy or breastfeeding. Insulin use

Intervention groups
The participants in the intervention group receive a multi-strain synbiotic supplement along with a weight loss diet. The participants in the control group also receive a weight loss diet along with a placebo.

Main outcome variables
Aspartate Aminotransferase

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240212060977N1**
Registration date: **2024-02-20, 1402/12/01**
Registration timing: **prospective**

Last update: **2024-02-20, 1402/12/01**
Update count: **0**
Registration date
2024-02-20, 1402/12/01

Registrant information
Name
Aryan M. Yazdani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3725 1001
Email address
aryanm_yazdani@sums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-04-13, 1403/01/25
Expected recruitment end date
2024-08-10, 1403/05/20
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of multi-strain synbiotic supplementation on insulin resistance, liver enzymes, inflammatory, and anthropometric indices in diabetic, obese, and overweight patients with non-alcoholic fatty liver disease

Public title

The effect of synbiotic supplementation in the treatment of fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having fatty liver (grade 2 or 3) Having diabetes or prediabetes (fasting blood sugar above 100) Being overweight or obese (BMI greater than 25) Aged 18 or higher from both male and female genders Not taking insulin Not being pregnant or breastfeeding Not suffering from certain diseases, including metabolic, respiratory, and kidney diseases Not taking antibiotics or probiotic or synbiotic supplements in the 3 months before the study

Exclusion criteria:

Suffering from certain diseases during study, including respiratory and kidney diseases Taking multivitamins while studying Consumption of less than 80% of prescribed supplements Consumption of other probiotics during the study The need to take antibiotics Getting pregnant Requiring need for insulin

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done using the random block method (1:1 ratio) for two groups (a control group and an intervention group). In this method, double blocks with rotation period will be created by a person outside the study. Then, a block is randomly selected to determine the groups assigned to the first two participants. The random block selection process is repeated to determine the random assignment sequence for the entire sample size. In order to hide the allocation, after determining the random sequence, these sequences named A and B are placed in sealed opaque envelopes for each participant. A person outside the study familiar with randomization will perform this process. During the study, as each participant enters the study, based on the order, an envelope is opened and the assigned group is determined.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Study groups and supplements will be labeled as A and B by an out-of-study person to blind the research team and participants. This naming will remain confidential until the end of the study. Supplements and placebos and their packaging are similar in appearance, size, color, and odor.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Schools of Health and Nutrition - Shiraz University of Medical Science

Street address

5th floor, Shiraz University Central Building, Islamic Republic Boulevard, Shiraz

City

Shiraz

Province

Fars

Postal code

84471-71946

Approval date

2024-02-12, 1402/11/23

Ethics committee reference number

IR.SUMS.SCHEANUT.REC.1402.154

Health conditions studied

1

Description of health condition studied

Fatty Liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

2

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Aspartate Aminotransferase

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

Standard enzymatic method

Secondary outcomes

1

Description

Alanine aminotransferase

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

Standard enzymatic method

2

Description

Fasting blood sugar

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

Standard enzymatic method

3

Description

Triglyceride

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

Standard enzymatic method

4

Description

Total cholestrol

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

Standard enzymatic method

5

Description

Total antioxidant capacity

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

Standard enzymatic method

6

Description

Low-density lipoprotein

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

Standard enzymatic method

7

Description

High-density lipoprotein

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

Standard enzymatic method

8

Description

C-reactive protein

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

ELISA method

9

Description

Alkaline Phosphates

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

Standard enzymatic method

10

Description

Glycated hemoglobin

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

Standard enzymatic method

11

Description

Fasting insulin

Timepoint
Before the start of the intervention and after the end of the intervention
Method of measurement
ELISA method

Intervention groups

1

Description
Intervention group: The intervention in this group includes receiving a synbiotic supplement (produced by Zist Takhmir Company) containing one billion CFU in each capsule of strains of Lactobacillus casei, Lactobacillus rhamnosus, Lactobacillus acidophilus, Bifidobacterium Bruhe, Bifidobacterium lactis, Bifidobacterium longum along with a weight loss diet. One daily supplement is taken after meal for 12 weeks.
Category
Treatment - Other

2

Description
Control group: The participants in this group take a placebo (from Zist Takhmir company) after meal, along with the weight loss diet for 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahari Clinic
Full name of responsible person
Mohammad Hasan Eftekhari
Street address
Motahari Clinic, Zand St., Namazi Square, Shiraz
City
Shiraz
Province
Fars
Postal code
71348714737
Phone
+98 71 3612 1001
Fax
Email
motahari@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Hashem Hashempour
Street address
5th floor, Shiraz University Central Building, Islamic Republic Boulevard, Shiraz
City
Shiraz
Province
Fars
Postal code
84471-71946
Phone
+98 71 3628 6426
Fax
+98 71 3628 7302
Email
viceres@shirazu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Aryan Mohammad Yazdani
Position
Masters Student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
School of Nutrition and Food Sciences, Razi Blvd., Shiraz
City
Shiraz
Province
Fars
Postal code
7153675500
Phone
+98 71 3725 1001
Email
Yazdani.2000.a@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mohammad Hassan Eftekhari

Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
School of Nutrition and Food Sciences, Razi Blvd., Shiraz

City
Shiraz

Province
Fars

Postal code
7153675500

Phone
+98 71 3725 1001

Email
h_eftekhari@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mohammad Ali Mohsenpour

Position
PhD Candidate

Latest degree
Master

Other areas of specialty/work
Nutrition

Street address
School of Nutrition and Food Sciences, Razi Blvd., hiraz

City
Shiraz

Province
Fars

Postal code
7153675500

Phone
+98 71 3725 1001

Email
mohammadali.mohsenpour@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