

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of probiotic yogurt with its supplementation on cognitive function, cortisol and serum superoxide dismutase in patients with type 2 diabetes

Protocol summary

Study aim

Comparison of the effect of probiotic yogurt with its supplementation on cognitive function, cortisol and serum superoxide dismutase in patients with T2 diabetes

Design

A controlled, parallel, double-blind, randomized, phase 3 clinical trial with a factorial group of 111 patients. The online site (www.sealedenvelope.com) was used for randomization

Settings and conduct

Patients from endocrinology, internal medicine, and nutrition clinics located in Sari will be included. Participants will not consume any probiotic dairy products for two weeks and will receive intervention for 12 weeks. At the beginning and end of the study, general characteristics, food intake, physical activity, and cognitive function with Mini-cog and color and word Stroop will be collected and evaluated. Cortisol and serum SOD will be measured. Participants, outcomes evaluation researchers, and technicians will not be informed about the intervention type. Normal and probiotic yogurt packages, supplements, and placebos will be prepared similarly to each other. A non-researcher will code them.

Participants/Inclusion and exclusion criteria

Inclusion criteria: T2 diabetes (at least two years); Hb-A1c equal to and less than 8.5; 50 to 69 years of age; Body mass index equal to and greater than 25 to 40; Blood pressure under control (<140/90 mmHg) in the last two months; The score of a brief cognitive screening test (Mini-Cog) \leq 2; Daily consumption of yogurt at least one serving; Education level of at least five classes
Exclusion criteria: Some of immunodeficiency; kidney; lung; digestive; thyroid diseases, and etc

Intervention groups

Group 1: a probiotic supplement capsule + 200 grams of regular yogurt per day Group 2: 200 grams of probiotic

yogurt + a placebo capsule per day Group 3: a placebo capsule + 200 grams of regular yogurt per day

Main outcome variables

Mini-cog test score; Color and word Stroop; Cortisol; Superoxide dismutase

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220621055238N1**

Registration date: **2023-01-08, 1401/10/18**

Registration timing: **retrospective**

Last update: **2023-01-08, 1401/10/18**

Update count: **0**

Registration date

2023-01-08, 1401/10/18

Registrant information

Name

Marsa Zaroudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 1762

Email address

marsazaroodi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-22, 1400/06/31

Expected recruitment end date

2022-08-05, 1401/05/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of probiotic yogurt with its supplementation on cognitive function, cortisol and serum superoxide dismutase in patients with type 2 diabetes

Public title

The effect of yogurt and probiotic supplement on the cognitive function of patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

50 to 69 years of age Body mass index equal to and greater than 25 to 40 Blood pressure under control (lower than 140/90 mmHg) in the last two months The score of a brief cognitive screening test (Mini-Cog) lower or equal of 2 Daily consumption of yogurt at least one serving Education level of at least five classes Hb-A1c equal to and less than 8.5 Type 2 diabetes (at least two years) Willingness to cooperate

Exclusion criteria:

Immune deficiency diseases Stage three and above of Chronic Kidney Disease (CKD) History of heart attack, congestive heart failure, stent placement Chronic Obstructive Pulmonary Disease (COPD) Stage three and above of fatty liver Inflammatory Bowel Disease (IBD), Irritable Bowel Syndrome (IBS), pernicious anemia and mal-absorption such as celiac disease and chronic pancreatitis Hypothalamic tumor Uncontrolled thyroid disease Parathyroid disease Adrenal disease Gum surgery under the supervision of a dentist Gastrointestinal surgeries Less than two years recovering from cancer Less than 3 months recovering from Covid-19 Neurological diseases such as seizures, mental retardation and stroke Comorbid psychiatric disorder such as Generalized Anxiety Disorder (GAD), depression, schizophrenia, dementia, Parkinson's Diseases, and bipolar Allergy Uncontrolled hypertriglyceridemia Allergy to cow's milk protein lactose intolerance Taking any medication other than oral medications for diabetes, blood pressure, dyslipidemia, aspirin, and levothyroxine in the last two months Taking antibiotics Having a special diet Regular consumption of dietary supplements (equal to or more than 3 times a week) other than vitamin D during the two months before the study alcohol consumption smoking Being pregnant or breastfeeding Participating in other medical studies

Age

From **50 years** old to **69 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **111**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization with six blocks will be used for randomization. According to the determined sample size of 111, 19 blocks of six will be produced using the online site (www.sealedenvelope.com). In order to apply concealment in the randomization process, numbered envelopes containing a random sequence will be used.

Blinding (investigator's opinion)

Double blinded

Blinding description

The people participating in the study, the researchers evaluating the results and the laboratory technicians will not be informed about the type of intervention until the end of the research. For this purpose, normal and probiotic yogurt packages, as well as probiotic supplement and its placebo, will be prepared similar to each other in terms of their appearance and labels, and someone other than the researcher will code them. In addition, the researcher will not know the allocation of the participants in each of the groups during the evaluation of the results.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

Street address

Faculty of Health, Iran University of Medical Sciences, Hemat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2021-03-14, 1399/12/24

Ethics committee reference number

IR.IUMS.REC.1399.1411

Health conditions studied

1

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

The score of the brief cognitive screening test (Mini-cog)

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (end of week 12)

Method of measurement

Mini-cog, a brief cognitive screening test

2

Description

The score of Stroop color-word

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (end of week 12)

Method of measurement

Stroop color-word test

Secondary outcomes

1

Description

Salivary cortisol

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (end of week 12)

Method of measurement

Immunoassay kit

2

Description

Superoxide Dismutase (SOD)

Timepoint

At the beginning of the study (before the start of the intervention) and at the end of the study (end of week 12)

Method of measurement

ELISA kit

Intervention groups

1

Description

Intervention group: The first intervention group: they receive one probiotic supplement capsule + 200 grams of plain yogurt per day for 12 weeks. Probiotic supplement is produced by Takgene Zist Company. This probiotic product is produced from two groups of bacteria, including Lactobacilli and Bifidobacteria, with a dose of two times ten to the power of eight Colony Forming Units (CFU) per capsule, and lactose and magnesium stearate are used as carriers. Plain yogurt is low-fat and produced by Amol Doosheh Dairy Products company. Yogurt is distributed weekly, which is provided to the participants in packages containing 14 glasses of 100 grams. Each 100 gram package of plain yogurt contains 51% calories, 3.6 grams of protein, 6 grams of carbohydrates and 1.4 grams of fat. Yogurt packages are delivered to the participants by maintaining the cold chain and at a temperature of minus 4 degrees Celsius. The people participating in the study are emphasized to store the yogurts immediately in the refrigerator.

Category

Treatment - Other

2

Description

Intervention group: The second intervention group: they will receive 200 grams of probiotic yogurt + one placebo capsule per day for 12 weeks. The probiotic yogurt of the present study is low-fat yogurt and it is produced by Amol Doosheh Dairy Products company. This probiotic product is produced from two groups of bacteria, including Lactobacilli and bifidobacteria, with a dose of two times ten to the power of eight Colony Forming Units (CFU). Yogurt is distributed weekly, which is provided to the participants in packages containing 14 glasses of 100 grams. Each 100 gram package of probiotic yogurt contains 51% calories, 3.6 grams of protein, 6 grams of carbohydrates and 1.4 grams of fat. Yogurt packages are delivered to the participants by maintaining the cold chain and at a temperature of minus 4 degrees Celsius. Participants are emphasized to store the yogurts immediately in the refrigerator. The placebo capsule is produced by Takgene Zist Company, which contains starch and is similar to the probiotic supplement in terms of appearance, color, size, and packaging.

Category

Treatment - Other

3

Description

Control group: they will receive 200 grams of plain yogurt + one placebo capsule per day for 12 weeks. Plain yogurt is low-fat and produced by Amol Doosheh Dairy Products company. Yogurt is distributed weekly, which is provided to the participants in packages containing 14 glasses of 100 grams. Each 100 gram package of plain yogurt contains 51% calories, 3.6 grams of protein, 6 grams of carbohydrates and 1.4 grams of fat. Yogurt packages are delivered to the participants by

maintaining the cold chain and at a temperature of minus 4 degrees Celsius. Participants are emphasized to store the yogurts immediately in the refrigerator. The placebo capsule is produced by Takgene Zist Company, which contains starch and is similar to the probiotic supplement in terms of appearance, color, size, and packaging.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Endocrinology, internal medicine and nutrition clinic

Full name of responsible person

Marsa Zaroudi

Street address

Unit 704, 7th floor, Exir medical building, between Tabarestan three-way junction and Darya 3, Dr. Beheshti Boulevard (Khazar), Sari, Mazandaran province, Iran

City

Sari

Province

Mazandaran

Postal code

4817753683

Phone

+98 11 3336 1762

Email

marsazaroodi@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Hossein keyvani

Street address

The fifth floor of the center building, Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, IRAN

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Phone

+98 21 8670 2503

Fax

+98 21 8862 2703

Email

keyvani.h@iums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Marsa Zaroudi

Position

دانشجو

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Left side building, Safarabad 12 Avenue, Farahabad Street

City

Sari

Province

Mazandaran

Postal code

4816135987

Phone

+98 11 3336 1762

Fax**Email**

marsazaroodi@yahoo.com

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

Iran University of Medical Sciences

Full name of responsible person

Marsa Zaroudi

Position

دانشجو

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Left side building, Safarabad 12 Avenue, Farahabad Street

City

Sari

Province

Mazandaran

Postal code

4816135987

Phone

+98 11 3336 1762

Fax**Email**

marsazaroody@yahoo.com

Mazandaran

Postal code

4816135987

Phone

+98 11 3336 1762

Fax**Email**

marsazaroody@yahoo.com

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

Iran University of Medical Sciences

Full name of responsible person

Marsa Zaroudi

Position

دانشجو

Latest degree

Master

Other areas of specialty/work

Nutrition

Street addressLeft side building, Safarabad 12 Avenue, Farahabad
Street**City**

Sari

Province**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