Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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) ≤ 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
marsazaroody@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
marsazaroody@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
۱۴۴۹۶۱۴۵۳۵

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
marsazaroody@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

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 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

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