

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Survey and Comparison of the effect of fortified yogurt enriched with fermented and non-fermented Spirulina Platensis extract on reducing oxidative stress in patients with type 2 diabetes mellitus

Protocol summary

Study aim

investigating the effect of yogurt enriched with spirulina platensis extract fermented with lactobacillus plantarium on reducing oxidative stress in patients with type 2 diabetes mellitus and comparing its results with the effect of yogurt enriched with unfermented spirulina platensis extract

Design

Clinical trial without control group - laboratory test before and after the intervention. , parallel groups, double-blind, randomized on 100 patients. The rand function of Excel software will used for randomization.

Settings and conduct

In this study, the effect of low-fat yogurt enriched with oral spirulina platensis algae on type 2 diabetic patients is investigated, and the effect of fermented and non-fermented types of spirulina used in low-fat yogurt in these patients is investigated. The location of the project in Iran is the city of Arak - diabetes clinics. 100 type 2 diabetic patients in the age group of 40 to 70 years enter the project and are randomly assigned to the first and second groups. Patients do not know the type of food powder used in low-fat yogurt.

Participants/Inclusion and exclusion criteria

Entry requirements: having type 2 diabetes for at least 2 years - age between 40 and 70 years Exit conditions: insulin injection

Intervention groups

100 people with diabetes participate in the plan. 50 people are randomly given yogurt containing spirulina algae extract for consumption and 50 people are given yogurt containing fermented spirulina extract. The laboratory criteria are evaluated before the intervention and after the intervention.

Main outcome variables

Examination of changes in fasting blood sugar; Malon dialdehyde level changes; changes in total antioxidant

capacity; Changes in the level of glutathione regeneration and changes in the level of high-sensitivity active protein C in the blood serum of type 2 diabetes patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220108053663N1**

Registration date: **2022-10-09, 1401/07/17**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-09, 1401/07/17**

Update count: **0**

Registration date

2022-10-09, 1401/07/17

Registrant information

Name

Ayda Ghafari Ashtiani

Name of organization / entity

Islamic Azad University, Science and Research Branch

Country

Iran (Islamic Republic of)

Phone

+98 86 3276 0036

Email address

aida_gh60@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-21, 1401/06/30

Expected recruitment end date

2022-10-22, 1401/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey and Comparison of the effect of fortified yogurt enriched with fermented and non-fermented Spirulina Platensis extract on reducing oxidative stress in patients with type 2 diabetes mellitus

Public title

Investigating the effect of Spirulina platensis algae in the treatment of diabetes

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Type 2 diabetes mellitus

Exclusion criteria:

Type1 diabetes mellitus Patients injecting insulin Age less than 40 and more than 70 years

AgeFrom **40 years** old to **70 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample sizeTarget sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description

This study is a double-blind randomized clinical trial study, which was considered by the diabetes clinic affiliated to Arak University of Medical Sciences to select patients with type 2 diabetes in the age group of 40-70 years. After voluntarily choosing 100 patients to participate in the study and providing explanations about the goals of the project and after obtaining their informed consent to participate in the study, a list of participants is prepared and coded. And the codes are entered in SPSS statistical software and using simple randomization method, people are divided into two groups of 50 people.

Blinding (investigator's opinion)

Double blinded

Blinding description

The intervention is a type of double-blind randomized clinical trial. None of the participants and examiners will know about the allocation of groups to the intervention under study. The intended intervention is similar in terms of appearance (smell, color, appearance, etc.).

Placebo

Not used

Assignment

Parallel

Other design features

In this study, spirulina algae is fermented and the effect of fermented type of algae is compared with non-fermented algae.

Secondary Ids

empty

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

Ethics Committee of Islamic Azad University Science and Research Unit

Street address

Islamic Azad University, Department of Science and Research - Sattari Blvd

City

Tehran

Province

Tehran

Postal code

1477893855

Approval date

2022-08-22, 1401/05/31

Ethics committee reference number

IR.IAU.SRB.REC.1401.094

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes mellitus

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes**1****Description**

Average changes in reduced glutathione levels in the blood serum of type 2 diabetics

Timepoint

Measurement of blood reduced glutathione levels before the intervention and 21 days after the intervention

Method of measurement

reduced glutathione blood level measurement kit

2**Description**

Average changes in fasting blood sugar levels in the blood serum of type 2 diabetics

Timepoint

Measurement of fasting blood sugar before the intervention and 21 days after the intervention

Method of measurement

fasting blood sugar measurement kit

3

Description

Average changes in high reactive protein C level in blood serum of type 2 diabetic patients

Timepoint

Measurement of C protein with high reactivity in blood serum before the intervention and 21 days after the intervention

Method of measurement

C- Reactive protein measurement kit

Secondary outcomes

1

Description

malondialdehyde(MDA)

Timepoint

Malondialdehyde content is measured before and 21 days after consumption of yogurt enriched with fermented and non-fermented Spirulina Platensis.

Method of measurement

diagnostic malondialdehyde assay kit

2

Description

Ferric Reducing Ability of Plasma(FRAP)

Timepoint

Before starting consumption and 21 days after starting consumption of yogurt enriched with fermented and non-fermented spirulina platensis, the antioxidant capacity of total plasma is measured.

Method of measurement

FRAP Detection Assay Kit

Intervention groups

1

Description

Intervention group: After the patients visited the diabetes clinic for the plan, full explanations about the objectives of the study will be given to them during a one-hour training session. Then, after obtaining their informed written permission and consent to voluntarily participate in the study, people are randomly divided into two groups of 50 people, 50 type 2 diabetic patients, daily 200 grams of low-fat yogurt containing 20 grams of non-fermented spirulina algae powder. It is suggested that the patient consumes 100 grams of yogurt in two meals for 21 days. Algae powder manufacturer is Berkeh Sabz Mad Asia Company, and it is one of the factories in the country and has a health license from the Vice-Chancellor of Food and Medicine of Arak University of

Medical Sciences.

Category

Treatment - Other

2

Description

Intervention group: After the patients visited the diabetes clinic for the plan, full explanations about the objectives of the study will be given to them during a one-hour training session. Then, after obtaining their informed written permission and consent to voluntarily participate in the study, people are randomly divided into two groups of 50 people, 50 type 2 diabetic patients, daily 200 grams of low-fat yogurt containing 20 grams of fermented spirulina algae powder. It is suggested that the patient consumes 100 grams of yogurt in two meals for 21 days. Algae powder manufacturer is Berkeh Sabz Mad Asia Company, and it is one of the factories in the country and has a health license from the Vice-Chancellor of Food and Medicine of Arak University of Medical Sciences.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Aida Ghaffari Nutrition and Diet Therapy Center

Full name of responsible person

Aida Ghaffari

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Ali Kamali

Street address

Sardasht Square, Arak Medical University

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3815937458

Phone
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Email
kalantari_neda@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Arak Medical University

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Anoosheh Sharifan

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
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Position
Student

Latest degree

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Nutrition

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Person responsible for updating data

Contact

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Master

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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

Title and more details about the data/document

The individual information of the participants without the names of the people, the spss file includes the results of fasting blood sugar, malondialdehyde, glutathione regeneration and the total antioxidant level of the blood serum of the patients can be shared. Statistical tests cannot be delegated.

When the data will become available and for how long

starting in september 2023

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

No special conditions are required.

From where data/document is obtainable

Refer to the email below. aida_gh60@yahoo.com

What processes are involved for a request to access data/document

Two weeks after submitting the application

Comments