Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Evaluation of oxidative stress biomarkers in type 2 diabetic patients consuming fermented and non-fermented spirulina platensis

Protocol summary

Study aim

Evaluation and comparison of malondialdehyde (MDA) level, reduced glutathione, non-enzymatic antioxidant capacity (FRAP), fasting blood sugar level (FBS) and HS-CRP level in patients receiving non-fermented spirulina platensis extract and fermented spirulina

Design

Clinical trial with control group, with parallel groups, one-way blinded , randomized on 150 patients.

Settings and conduct

In this study, the effect of oral Spirulina platensis on type 2 diabetic patients and also the effect of fermented and non-fermented spirulina in these patients will investigate. location of study will be in Iran-Arak diabetes clinics. 150 type 2 diabetic patients in the age group of 50 to 70 years will enterto study and randomly devided to tree group by block method. Patients do not know the type of food powder consumed.

Participants/Inclusion and exclusion criteria

Patients with type 2 diabetes in the age group of 50 to 70 years, whether male or female

Intervention groups

This study is a randomized clinical trial in which patients with type 2 diabetes in the age group of 50 to 70 years will be included. 150 patients are randomly divided into 3 groups by block method. The first group received fermented Spirulina Platensis (n = 50) The second group received non-fermented Spirulina Platensis (n = 50) and the third group is control group(n= 50), in the first group 4 g of fermented Spirulina Platensis twice a day for 7 days , In the second group, 4 grams of non-fermented spirulina platensis will be given twice a day for 7 days and in the third group, placebo will be given, 4 g wheat bran twice a day for 7 days

Main outcome variables

Reducing the effects of oxidative stress in patients with type 2 diabetes by consuming the Spirulina platensis. Comparison of reducing the effects of oxidative stress in patients with type 2 diabetes with the use of fermented and unfermented Spirulina platensis.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220109053671N1**
Registration date: **2022-02-13, 1400/11/24**
Registration timing: **prospective**

Last update: **2022-02-13, 1400/11/24**
Update count: **0**

Registration date

2022-02-13, 1400/11/24

Registrant information

Name

Morteza Qaribi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 1041

Email address

dr.gharibi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2022-05-20, 1401/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of oxidative stress biomarkers in type 2 diabetic patients consuming fermented and non-fermented spirulina platensis

Public title
Evaluation of antioxidant effect of Spirulina platensis in type 2 diabetic patients

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Having type 2 diabetes that is at least 2 years old diabetics

Exclusion criteria:
People with type 1 diabetes People under the age of 49 and over 70 years old

Age
From **50 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method: in this method, from the list of diabetic patients in the clinic, diabetic patients between 50 and 70 years old who have had diabetes for at least one year are separated, then the prepared list is numbered and entered into SPSS software. In SPSS software, 3 groups are selected by simple random sampling calculations.

Blinding (investigator's opinion)
Double blinded

Blinding description
According to the sampling method, both the spirulina group and the placebo group are unaware of the supplement they are taking. The examiner also does not know which supplement each group took.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
University Complex of the Great Prophet (PBUH)-Basij Square- Sardasht

City
Arak

Province
Markazi

Postal code
6341738481

Approval date
2022-01-17, 1400/10/27

Ethics committee reference number
IR.ARAKMU.REC.1400.255

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
Mean of fast blood glucose

Timepoint
Day before and eight days after starting the study

Method of measurement
Through special clinical assessment kits

2

Description
HS-CRP

Timepoint
Day before and eight day after starting the study

Method of measurement
Through special clinical assessment kits

3

Description
Malondialdehyde

Timepoint
Day before and eight days after starting the study

Method of measurement
Through special clinical assessment kits

4

Description

Reduced Glutathione

Timepoint

Day before and eight days after starting the study

Method of measurement

Through special clinical assessment kits

5

Description

Non-enzymatic antioxidant capacity

Timepoint

Day before and eight days after starting the study

Method of measurement

Through special clinical assessment kits

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Presenting 8 g of oral Spirulina platensis algae powder in two meals of 4 g per day to the patient for 7 days continuously

Category

Treatment - Other

2

Description

Intervention group: Presenting 8 g of Spirulina platensis algae powder fermented with Lactobacillus plantarum in two meals of 4 g / day for 7 days

Category

Treatment - Other

3

Description

Control group: Presenting 8 grams of edible wheat bran powder in two 4 gram meals per day to the patient for 7 days

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Clinic

Full name of responsible person

Dr Faezeh Soufian

Street address

Shahid Shiroodi street

City

Arak

Province

Markazi

Postal code

3813899589

Phone

+98 86 3402 0021

Fax

+98 86 3402 0030

Email

faezesoufiyan@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Ali Kamali

Street address

Payambar University Complex- Basij Square - Sardasht

City

Arak

Province

Markazi

Postal code

6341738481

Phone

+98 86 3417 3520

Fax

+98 86 3147 3521

Email

info@arakmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Morteza Gharibi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work
Emergency Medicine

Street address
University Complex of the Great Prophet (PBUH)-Basij Square- Sardasht- Arak- Iran

City
Arak

Province
Markazi

Postal code
6341738481

Phone
+98 86 3276 0036

Email
morteza.qaribi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Dr Morteza Gharibi

Position
Associate professo

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

Street address
University Complex of the Great Prophet (PBUH)-Basij Square- Sardasht- Arak- Iran

City
Arak

Province
Markazi

Postal code
3815937458

Phone
+98 86 3276 0036

Email
morteza.qaribi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Morteza Gharibi

Position
Associate professor

Latest degree
Specialist

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Markazi

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morteza.qaribi@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Articles extracted from the project are shared in a reputable journal. The article contains clinical trial data and will not refer to a specific person.

When the data will become available and for how long
Access period starts 6 months after the results are published

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 considered

From where data/document is obtainable
Applicants should send an email to Dr. Morteza Gharibi to receive information/ morteza.qaribi@gmail.com

What processes are involved for a request to access data/document
The applicant must send an e-mail to Dr. Morteza Gharibi stating his intentions in requesting information. The sent email will be checked and answered within a week.

Comments