

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Investigating the effect of sauce prepared with spirulina algae on anthropometric indicators, glycemic markers, lipid profile, malondialdehyde and appetite in patients with type 2 diabetes: a double-blind clinical trial

Protocol summary

Study aim

Determination the Effect of Sauce prepared with Spirulina Algae on Anthropometric Indicators, Glycemic Markers, Lipid Profile, Malondialdehyde and Appetite in Patients with Type 2 Diabetes

Design

46 patients with type 2 diabetes were divided into two groups using Stratified randomization. The study is a double blind clinical trial with control group

Settings and conduct

Patients referred to Ghotbeddin Shirazi Clinic will be enrolled in the study by census method. After reviewing the inclusion criteria, 5 cc of blood will be taken from patients. The questionnaires of demographic, physical activity, appetite and a three-day feed registration form will be completed. The Sauce will be delivered monthly to patients. In order to double-blind the study, a third party encodes the packages of cakes prepared as A and B.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with type 2 diabetes aged 30-60 years who do not use insulin. Exclusion criteria: Pregnancy, lactation, history of cardiovascular disease, liver, kidney and thyroid disorders.

Intervention groups

First group: Individuals receiving the Spirulina sauce
Second group (Control group): Individuals receiving the sauce without Spirulina

Main outcome variables

Fasting blood glucose; Insulin; Hemoglobin A1c; Insulin resistance; Appetite

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191126045515N1**

Registration date: **2020-07-18, 1399/04/28**

Registration timing: **retrospective**

Last update: **2020-07-18, 1399/04/28**

Update count: **0**

Registration date

2020-07-18, 1399/04/28

Registrant information

Name

Mojtaba Rezaiyan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77 3762 3282

Email address

rezaiyan@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-31, 1398/10/10

Expected recruitment end date

2020-02-29, 1398/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of sauce prepared with spirulina algae on anthropometric indicators, glycemic markers,

lipid profile, malondialdehyde and appetite in patients with type 2 diabetes: a double-blind clinical trial

Public title

Investigating the effect of spirulina algae in type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with type 2 diabetes (doctor's diagnosis) Fasting blood sugar higher than 130 Not using insulin Age between 30 and 60 years

Exclusion criteria:

Suffering from cardiovascular, liver, kidney and thyroid disorders Specific medical conditions that require specific diet and exercise changes Participate in other studies over the past 6 months Use any supplements or specific diets Pregnancy and lactation Alcohol consumption and smoking

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization based on the method of reversible blocks In this scheme, randomization based on the method of reversible blocks is carried out In the way that 4 blocks will be created. These blocks are then randomly placed in two rows, male and female. Through classifying blocks by the gender, at the end of sampling we will have an equal number of male and female participants in both groups (A and B), thereby modifying the effect of gender distortion.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the first step is to allocate a specific pilot that will be used to produce products containing Spirulina and without Spirulina in a factory and will be monitored by the project scientific consultant (food industry specialist) and the researcher to ensure optimal production conditions. After that, the factory is asked to produce a sufficient number of products in the same packaging and different labels A or B. Consultant of the project and production manager are the only people who are aware of the type of packaged products. As a result, the researcher and participants will be blinded. The products are delivered from the factory after production and are given to the patients immediately. In order to concealment, all code predicted by random allocation

software is placed in pockets respectively. Pockets related to a women's accidental block are placed in the first box and pockets related to a men's accidental block are placed in the second box. The lids of the boxes are designed so that only the top pocket can be removed each time. The first pocket taken from the women's box will be assigned to the first female client, who will determine which group (A or B) this person will be after opening. The same goes for men. By doing so, the researcher cannot predict which group the next clients will fall into and the interviewer's bias will be curbed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Dastgheib Dormitory, Eram Square

City

Shiraz

Province

Fars

Postal code

7194684695

Approval date

2019-08-06, 1398/05/15

Ethics committee reference number

IR.SUMS.REC.1398.739

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

Fasting blood sugar

Timepoint

Before and after intervention

Method of measurement

By the means of Pars Azmoon Company kit and auto analyzer

2

Description

Insulin

Timepoint

Before and after intervention

Method of measurement

By Diameter Company Kit

3

Description

Hemoglobin A1c

Timepoint

Before and after intervention

Method of measurement

By diazyme kit

4

Description

Insulin resistance

Timepoint

Before and after intervention

Method of measurement

With Homeostatic Model Assessment for Insulin

Resistance index and formula

5

Description

Appetite

Timepoint

Before and after intervention

Method of measurement

With Visual analogue scales questionnaire

6

Description

Serum lipid profile

Timepoint

Before and after intervention

Method of measurement

By the means of Pars Azmoon Company kit and auto analyzer

7

Description

Malondialdehyde

Timepoint

Before and after intervention

Method of measurement

Thiobarbituric acid method

8

Description

Weight

Timepoint

Before and after intervention

Method of measurement

Digital scales

9

Description

Body composition

Timepoint

Before and after the intervention

Method of measurement

Bioelectric impedance analysis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group receiving the spirulina algae sauce would use the sauce containing 2 grams of Spirulina per day up to 2 months. The products were produced in Tiondasht Keshto Sanaat company

Category

Treatment - Other

2

Description

Control group: The group receiving the sauce without Spirulina algae

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghotbeddin Shirazi Clinic

Full name of responsible person

Javad Hemmatyar

Street address

East Fakhraabad Street, Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

Street address

Seventh Floor, Office of Research and Technology,
Central Building of Shiraz University of Medical
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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

Mojtaba Rezaian

Position

Msc student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

I haven't decided yet. The release schedule is not clear yet.

When the data will become available and for how long

I haven't decided yet. The release schedule is not clear yet.

To whom data/document is available

I haven't decided yet. The release schedule is not clear yet.

Under which criteria data/document could be used

I haven't decided yet. The release schedule is not clear yet.

From where data/document is obtainable

I haven't decided yet. The release schedule is not clear yet.

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

I haven't decided yet. The release schedule is not clear yet.

Comments