Clinical Trial Protocol
Iranian Registry of Clinical Trials
26 Jul 2021

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)

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+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,
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 Fakhrabad Street, Shiraz

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Shiraz

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7163854733

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Web page address
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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 Sciences, Zand Street, Shiraz
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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 Rezaiyan
Position
Msc student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Latest degree
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Person responsible for updating data

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City
Shiraz
Province
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