Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the effects of rice bran oil capsule on glycemic indices, antioxidant and inflammatory indicators patients with type 2 diabetes: Double-blinded randomized clinical trial

Protocol summary

Study aim

Determination of the effects of rice bran oil capsule on glycemic indices, antioxidant and inflammatory indicators patients with type 2 diabetes

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 50 patients to allocate consumption to the subjects will use the randomized block method. The website http://www.randomization.com will also be used for randomization.

Settings and conduct

Fifty patients with type 2 diabetes referred to the outpatient clinic of Razi Medical Education Center in Rasht. With personal consent, they will enter the study after completing the informed consent form, taking into account the entry and exit criteria. Patients in two groups of twenty-five will be subjected to intervention with one capsule containing one gram of rice bran oil along with a standard diet, and the control group will be given a placebo capsule along with a standard diet. The sampling method will be easy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients diagnosed with type 2 diabetes under drug therapy in the age range of 20 to 70 years, serum glucose more than 110 mg/dL , body mass index in the range of 25-30, hemoglobin E1C maximum 9%.Exclusion criteria: use of insulin, use of vitamin and mineral supplements, antioxidants, fiber supplements, omega-3, history of kidney disease, kidney stones, digestive diseases, gallstones, autoimmune diseases, Current consumption of alcohol

Intervention groups

Intervention group: Patients with type 2 diabetes will be prescribed one capsule containing one gram of rice bran oil daily for 12 weeks in addition to the standard diet that includes 53% carbohydrates, 17% protein and 30% fat.

Control: Patients with type 2 diabetes are prescribed a placebo capsule daily for 12 weeks in addition to the standard diet.

Main outcome variables

Glycemic, antioxidant and inflammatory control indicators

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180205038626N12**
Registration date: **2023-08-21, 1402/05/30**
Registration timing: **prospective**

Last update: **2023-08-21, 1402/05/30**
Update count: **0**

Registration date

2023-08-21, 1402/05/30

Registrant information

Name

Zahra Ahmadnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-06, 1402/06/15

Expected recruitment end date

2024-08-05, 1403/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of rice bran oil capsule on glycemic indices, antioxidant and inflammatory indicators patients with type 2 diabetes: Double-blinded randomized clinical trial

Public title

effects of rice bran oil capsule on glycemic indices, antioxidant and inflammatory indicators patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with an age range of 20 to 70 years Patients diagnosed with type 2 diabetes under drug therapy Serum glucose greater than 110 mg/dL Hemoglobin A1C maximum 9% Body mass index in the range of 25-30 Not using vitamin and mineral supplements, antioxidants, fiber supplements, omega-3 No history of kidney disease, kidney stones, digestive diseases, gallstones, and autoimmune diseases No current consumption of alcohol Not taking insulin

Exclusion criteria:

Change in the patient's disease treatment plan during the study Changing the type of drugs used, effective factors studied Reluctance to continue the study or cause any dissatisfaction regarding the taste of the oil or participation in the study

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of sampling and randomization of the two-blind, parallel-group clinical trial study will be stratified block randomization. At first, participants were classified into two classes according to age (20 to 45 years and between 45 to 70 years) and then each person was randomly assigned to the intervention or control group using 1: 4 random blocks. Took. In this method, each group will be assigned one of the letters A or B. The website will also be used for randomization. The list of codes obtained from this website will be provided to the researchers, and each referring patient who met the inclusion criteria and did not meet the inclusion criteria and was willing to participate in the study, first entered the desired age group and based on The assigned code A or B enters the design. For concealment, in this study, random allocation concealment, which is the method used to execute a random sequence on the study participants, will be used in such a way that the assigned group is not known before the individual is assigned. In this way, using opaque envelopes sealed with a random sequence, in this method, each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Since the capsules containing rice bran oil and placebo have been tried to be completely similar to each other due to the similarity in taste, taste, aroma and smell, the patients receiving and the researchers providing the supplements are of the type of supplement that each participant receives. They will not be aware.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Technology & Research Vice-chancellor of University; Shahid Siadati St; Namjoo St., Rasht

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2023-07-26, 1402/05/04

Ethics committee reference number

IR.GUMS.REC.1402.253

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
Serum lipid profile levels (triglycerides, total cholesterol, LDL-C and HDL-C)
Timepoint
At the beginning of the study and 12 weeks later
Method of measurement
BT2000 device

2

Description
Fasting blood sugar
Timepoint
At the beginning of the study and 12 weeks later
Method of measurement
BT2000 device

3

Description
Serum insulin
Timepoint
At the beginning of the study and 12 weeks later
Method of measurement
BT2000 device

4

Description
Glycosylated hemoglobin
Timepoint
At the beginning of the study and 12 weeks later
Method of measurement
ELISA device

5

Description
Erythrocyte sedimentation rate
Timepoint
At the beginning of the study and 12 weeks later
Method of measurement
ELISA device

6

Description
Prothrombin Time
Timepoint
At the beginning of the study and 12 weeks later
Method of measurement
ELISA device

7

Description
Partial Thromboplastin Time
Timepoint
At the beginning of the study and 12 weeks later
Method of measurement
ELISA device

8

Description
Adropin
Timepoint
At the beginning of the study and 12 weeks later
Method of measurement
ELISA device

9

Description
Omentin-1
Timepoint
At the beginning of the study and 12 weeks later
Method of measurement
ELISA device

10

Description
Glutathione peroxidase activity
Timepoint
At the beginning of the study and 12 weeks later
Method of measurement
ELISA device

11

Description
Glutathione reductase activity
Timepoint
At the beginning of the study and 12 weeks later
Method of measurement
ELISA device

12

Description
Superoxide dismutase activity
Timepoint
At the beginning of the study and 12 weeks later
Method of measurement
ELISA device

13

Description
Catalase activity
Timepoint

At the beginning of the study and 12 weeks later

Method of measurement

ELISA device

14

Description

Paraoxonase activity

Timepoint

At the beginning of the study and 12 weeks later

Method of measurement

ELISA device

15

Description

Vitamin E

Timepoint

At the beginning of the study and 12 weeks later

Method of measurement

ELISA device

16

Description

Xanthine oxidase activity

Timepoint

At the beginning of the study and 12 weeks later

Method of measurement

ELISA device

17

Description

HS - C-reactive protein

Timepoint

At the beginning of the study and 12 weeks later

Method of measurement

ELISA device

18

Description

Total antioxidant activity

Timepoint

At the beginning of the study and 12 weeks later

Method of measurement

ELISA device

19

Description

Estimated Glomerular Filtration Rate

Timepoint

At the beginning of the study and 12 weeks later

Method of measurement

Laboratory formula-measurement

20

Description

C-Peptide

Timepoint

At the beginning of the study and 12 weeks later

Method of measurement

ELISA device

Secondary outcomes

1

Description

Mean systolic and diastolic blood pressure

Timepoint

At the beginning of the study and 12 weeks later

Method of measurement

Pressure indicator

2

Description

Body mass index

Timepoint

At the beginning of the study and 12 weeks later

Method of measurement

Centimeter and scales

Intervention groups

1

Description

Intervention group: patients with type 2 diabetes, for 12 weeks, in addition to the standard diet, which includes 53% carbohydrates, 17% protein, and 30% fat, a nutritional consultant will provide the patients with a capsule containing Rice bran oil is prescribed and they are asked to consume one capsule of rice bran oil daily.

Category

Treatment - Other

2

Description

Control group: patients with type 2 diabetes, for 12 weeks, in addition to the standard diet, which includes 53% carbohydrates, 17% protein, and 30% fat, a nutritional consultant will provide the patients with a placebo capsule. It is prescribed and they are asked to take a placebo capsule daily.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Marjan Mahdavi Roshan

Street address

Razi Educational and Medical Center, Sardar Jangal St.

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohammadreza Naghipour
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Technology & Research Vice-chancellor of University; Shahid Siadati St; Namjoo St., Rasht
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naghi@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
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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