Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effects of rice bran powder administration on cardiovascular risk factors in adult patients with metabolic syndrome: A Randomized Controlled Open Label Trial

Protocol summary

Study aim
Determining the effects of rice bran powder on cardiovascular risk factors in adult patients with metabolic syndrome

Design
Clinical trial with control group, with parallel groups, without blinding, 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 metabolic syndrome referred to the outpatient clinic of Dr. Heshmat Heart Training Center will be admitted to the study with personal consent after completing the informed consent form, taking into account the inclusion and exclusion criteria. Patients in two groups of 25 will be intervened with rice bran powder (15 grams per day equivalent to 1 tablespoon) and standard diet or standard diet alone (as a control group). The sampling method will be easy.

Participants/Inclusion and exclusion criteria
Patients with an age range of 20 to 70 years ,Patients with metabolic syndrome, Do not use vitamin and mineral supplements, antioxidants, fiber supplements, omega 3,No history of kidney disease, kidney stones, gastrointestinal diseases, gallstones, and autoimmune diseases ,Current consumption of alcohol

Intervention groups
Intervention group: Patients with metabolic syndrome will consume 15 grams of bran powder, which is equivalent to 1 tablespoon of bran powder prepared by Giltaz company, for 8 weeks, along with their lunch or salad with rice. Control group: Patients with metabolic syndrome will be prescribed only a standard diet for 8 weeks. According to the formula, a standard diet consisting of 55 Percent carbohydrates, 18 Percent protein and 27 Percent fat will be provided to patients by a nutrition consultant.

Main outcome variables
Lipid Profiles (Triglycerides, Total Cholesterol, LDL-C and HDL-C) Apo A1 and Apo B100 fasting blood sugar CRP D-dimer

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180205038626N11**
Registration date: **2021-11-27, 1400/09/06**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-27, 1400/09/06**
Update count: **0**

Registration date
2021-11-27, 1400/09/06

Registrant information

Name
Zahra Ahmadnia
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 13 3361 8177
Email address
zahmadnia@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-22, 1400/09/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of rice bran powder administration on cardiovascular risk factors in adult patients with metabolic syndrome: A Randomized Controlled Open Label Trial

Public title

Evaluation of the effects of rice bran powder administration on cardiovascular risk factors in adult patients with metabolic syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with an age range of 20 to 70 years Patients with metabolic syndrome Do not use vitamin and mineral supplements, antioxidants, fiber supplements, omega 3 No history of kidney disease, kidney stones, gastrointestinal diseases, gallstones, and autoimmune diseases No current consumption of alcohol

Exclusion criteria:

Changes in the patient's treatment plan during the study Changing the type of effective drugs used factors studied Reluctance to continue the study or to cause any dissatisfaction with the taste of the powder or to participate in the study

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling and randomization The clinical trial study of two parallel groups of open label will be classified by block random sampling method. 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)

Not blinded

Blinding description

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

2021-11-10, 1400/08/19

Ethics committee reference number

IR.GUMS.REC.1400.388

Health conditions studied

1

Description of health condition studied

Metabolic syndrome

ICD-10 code

E88.81

ICD-10 code description

Metabolic syndrome

Primary outcomes

1

Description
Serum lipid profile levels (triglycerides, total cholesterol, LDL-C and HDL-C)
Timepoint
At the beginning of the study and 8 weeks later
Method of measurement
BT2000 device

2

Description
Serum levels of Apo A1 and Apo B100
Timepoint
At the beginning of the study and 8 weeks later
Method of measurement
Nephrometric device

3

Description
Fasting blood sugar
Timepoint
At the beginning of the study and 8 weeks later
Method of measurement
BT2000 device

4

Description
CRP
Timepoint
At the beginning of the study and 8 weeks later
Method of measurement
BT2000 device

5

Description
D-dimer
Timepoint
At the beginning of the study and 8 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 8 weeks later
Method of measurement
Pressure indicator

2

Description
Body mass index
Timepoint
At the beginning of the study and 8 weeks later
Method of measurement
Centimeter and scales

3

Description
Waist
Timepoint
At the beginning of the study and 8 weeks later
Method of measurement
Centimeter

Intervention groups

1

Description
Intervention group: Patients with metabolic syndrome will be given 15 grams of rice bran equivalent to 1 tablespoon of Giltaz daily for eight weeks.
Category
Prevention

2

Description
Control group: A standard diet will be prescribed for 8 weeks. According to a standard diet containing 55% carbohydrates, 18% protein and 27% fat, a nutrition consultant will provide patients with.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Heshmat hospital
Full name of responsible person
Marjan Mahdavi Roshan
Street address
15 Khordad St., next to the Management and Planning Organization of Gilan Province, Dr. Heshmat Heart Training and Treatment Center
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gums.icrc@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
محمدرضا نقی پور

Street address
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
Rasht University of Medical Sciences

Full name of responsible person
Zahra ahmadnia

Position
Nurse

Latest degree
Master

Other areas of specialty/work
Nursery

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Dr. Heshmat Hospital; Bayani St; Mosala Square; Rasht.

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Person responsible for scientific inquiries

Contact

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Rasht University of Medical Sciences

Full name of responsible person
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Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Marjanmahdavi60@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Zahra ahmadnia

Position
Nurse

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Nursery

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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

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

Information on the main outcome

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 institutions

Under which criteria data/document could be used

Request to receive unidentifiable personal data or other documents

From where data/document is obtainable

Marjan Mahdavi Roshan

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

By email to Dr.Marjan Mahdavi Roshan

Comments