

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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	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 <u>1</u> 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
Age From 20 years old to 70 years old Gender Both Phase 2 Groups that have been masked <i>No information</i> 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	Health conditions studied <u>1</u> 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

محمد رضا تقی پور

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Technology & Research Vice-chancellor of University;
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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

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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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

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