

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study on the Effect of Rice Bran Oil on Clinical and Biochemical Cardiovascular Parameters in Patients with Coronary Artery Disease

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Determining the effect of rice bran oil on clinical and biochemical cardiovascular parameters in patients with coronary artery disease

Last update: **2019-04-27, 1398/02/07**

Update count: **0**

Registration date

2019-04-27, 1398/02/07

Design

Clinical trial (Phase II) with 2 groups (control and intervention), with parallel groups, double blinded, randomized. Sample size is 40.

Registrant information

Name

Marjan Mahdaviroshan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3361 8177

Email address

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Settings and conduct

The samples will be selected from cardiac patients referring to Heshmat heart center in 2019-2020 after completing the informed consent . The study design is double blinded. Sampling method will be done by balanced random block rather than the allocation of the groups. The lipid lowering drugs will not be discontinued in either of the two groups, and the type and dosage of the drug will be matched in two groups under the supervision of cardiologist .

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: 20-70 year old patients with coronary reocclusion that have recently angioplasty. Non-inclusion criteria: Using vitamin and mineral supplements; antioxidants; fiber supplement; omega-3; history of kidney disease; current consumption of alcoholic beverages.

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2020-03-19, 1398/12/29

Intervention groups

Intervention group: rice bran oil, 30 grams daily Control group: sunflower oil, 30 g daily

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Weight ; systolic and diastolic BP; cholesterol; TG; LDL; HDL;hSCRIP ;TNF-a, uricacid ; FBS; EF index

Trial completion date

empty

General information

Scientific title

Study on the Effect of Rice Bran Oil on Clinical and Biochemical Cardiovascular Parameters in Patients with Coronary Artery Disease

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190313043045N1**

Registration date: **2019-04-27, 1398/02/07**

Public title

Effect of Rice Bran Oil on Clinical and Biochemical Cardiovascular Parameters

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 20-70 years old Recently undergoing angioplasty with coronary artery reocclusion

Exclusion criteria:

Use of vitamin and mineral supplements, antioxidants, fiber supplement, omega-3 Having a history of kidney disease Current consumption of alcoholic beverages

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are randomly divided into two groups. Block randomization method is used to randomly dividing the subjects into two intervention and placebo groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study type is double blinded. Sampling method will be done by balanced random block design than allocation of the groups. The lipid lowering drugs will not be discontinued in either of the two groups, and the type and dosage of the drug will be matched in two groups under the supervision of cardiologists .

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

Dr. Heshmat Hospital; Baniyani Street; Masala Square; Rasht

City

Rasht

Province

Guilan

Postal code

4193955588

Approval date

2019-02-02, 1397/11/13

Ethics committee reference number

IR.GUMS.REC.1397.485

Health conditions studied

1

Description of health condition studied

Coronary Artery Disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery with unstable angina pectoris

Primary outcomes

1

Description

Weight

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

scale

2

Description

systolic and diastolic blood pressure

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

barometer

3

Description

total cholesterol

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

All the kits of the Pars laboratory test model Hitaeh viv

4

Description

TG, LDL, HDL, HSCRP, TNF- α

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

All the kits of the Pars laboratory test model Hitaeh viv

5

Description

uric acid

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

All the kits of the Pars laboratory test model Hitaeh viv

6

Description

fasting glucose

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

All the kits of the Pars laboratory test model Hitaeh viv

7

Description

EF score

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

echocardiography

8

Description

severity of vascular involvement.

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

severity of vascular involvement with measured syntax will be.

Secondary outcomes

1

Description

ندارد

Timepoint

ندارد

Method of measurement

ندارد

Intervention groups

1

Description

Intervention group: consuming rice bran oil, 30 grams daily, for 8 weeks.

Category

Treatment - Other

2

Description

Control group: consuming sunflower oil, 30 grams daily, for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hashmat Hospital in Rasht

Full name of responsible person

Marjan Mahdavi Roshan

Street address

Dr. Heshmat Hospital; Baniyani Street; Masala Square; Rasht

City

Rasht

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Postal code

4193955588

Phone

+98 13 3361 8177

Email

heshmat@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Giltase Food Industry Co

Full name of responsible person

Esmael Fadaei Chafi

Street address

Balachaf; Chamkhale; Chaf; Langeruod

City

Rasht

Province

Guilan

Postal code

4193955588

Phone

+98 13 3361 8177

Email

hadi-giltaz@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Giltase Food Industry Co

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Marjan Mahdavi Roshan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Marjan Mahdavi Roshan

Position

Associate professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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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