Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Oct 2026

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

Protocol summary

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

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

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 .

Participants/Inclusion and exclusion criteria
Inclusion criteria: 20-70 year old patients with coronary reocculsion 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.

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

Main outcome variables
Weight ; systolic and diastolic BP; cholesterol; TG; LDL; HDL;hSCRP ;TNF-a, uricacid ; FBS; EF index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190313043045N1**
Registration date: **2019-04-27, 1398/02/07**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-27, 1398/02/07**
Update count: **0**

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

Registrant information

Name
Marjan Mahdaviroshan

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 13 3361 8177

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mahdaviroshan@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-21, 1398/01/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

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

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 reocclussion
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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+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
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Postal code
4193955588
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+98 13 3361 8177
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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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Dr. Heshmat Hospital; Baniyani Street; Masala Square; Rasht

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Marjan Mahdavi Roshan

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Associate professor

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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