

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of rice husk and rice bran in combination with limited energy diet on anthropometry parameters, lipid profiles and inflammatory factors in overweight and obese adults

Protocol summary

Summary

The present study aimed to comparison of the effect of rice husk and rice bran in combination with limited energy diet on anthropometry parameters, lipid profiles and inflammatory factors in healthy overweight and obese adults, general inclusion criteria are men and women 20-50 years with low physical activity and exclusion criteria are having heavy physical activity and chronic disease such as diabetes, 105 of the Shahid Rajaei Hospital staff assigned to one of three diet arms (at energy requirements 500 kcal lower than for weight maintenance): (1) low caloric diet (control); (2) low caloric diet with rice bran (70 g rice bran) or (3) low caloric diet with rice hull(25 g rice husk), this study following for 12 weeks to decrease weight and waist circumference in overweight and obese adults.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015040721652N1**

Registration date: **2015-05-30, 1394/03/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-30, 1394/03/09

Registrant information

Name

Fahimeh Edrissi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-01-21, 1393/11/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of rice husk and rice bran in combination with limited energy diet on anthropometry parameters, lipid profiles and inflammatory factors in overweight and obese adults

Public title

the effect of consuming rice husk and rice bran on weight loss

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: healthy men and women 20-50 years with BMI>25; stable weight for more than 6 months; low physical activity. Exclusion criteria: hormone therapy; taking supplements; lipid-lowering medication; weight-lowering medication; smoking; alcoholism; major illnesses (including diabetes mellitus; chronic renal failure; uncontrolled hypertension (>180/100 mm Hg));

Iron deficiency; pregnancy/ lactation; fiber allergies; using low caloric diet at 6 months; reporting a weight change of 5 kg during the previous 6 months; heavy physical activity.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Karim Khan
Zand Blvd, Shiraz

City

Shiraz

Postal code

Approval date

2015-03-08, 1393/12/17

Ethics committee reference number

7419-9379-CT

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

2

Description of health condition studied

overweight

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description

weight

Timepoint

at baseline and at 12 weeks following end of intervention

Method of measurement

Seca scale

2

Description

Waist circumference

Timepoint

at baseline and at 12 weeks following end of intervention

Method of measurement

nonstretchable tape measure

Secondary outcomes

1

Description

total cholesterol

Timepoint

at baseline and at 12 weeks following end of intervention

Method of measurement

autoanalyzer bt1500

2

Description

triglycerides

Timepoint

at baseline and at 12 weeks following end of intervention

Method of measurement

autoanalyzer bt1500

3

Description

HDL- cholesterol

Timepoint

at baseline and at 12 weeks following end of intervention

Method of measurement

autoanalyzer bt1500

4

Description

LDL-cholesterol

Timepoint

at baseline and at 12 weeks following end of intervention

Method of measurement

autoanalyzer bt1500

5

Description

CRP

Timepoint

at baseline and at 12 weeks following end of intervention

Method of measurement

ELISA

6

Description

IL-6

Timepoint

at baseline and at 12 weeks following end of intervention

Method of measurement

colorimetry

Intervention groups

1

Description

rice husk(25gr/ daily) in combination with limited energy diet for 12 weeks

Category

Treatment - Other

2

Description

rice bran(70 gr/daily) in combination with limited energy diet for 12 weeks

Category

Treatment - Other

3

Description

limited energy diet

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Trauma Center (Shahid Rajaee Hospital)

Full name of responsible person

Fahimeh Edrissi

Street address

Shahid Rajaee Hospital, Chamran Blvd, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Basir Hashemi

Street address

Shiraz University of Medical Sciences, Karim Khan Zand Blvd, Shiraz

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Nutrition and Food Sciences

Full name of responsible person

Fahimeh Edrissi

Position

MS Student of Nutrition

Other areas of specialty/work

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Person responsible for scientific inquiries

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Mosa Salehi

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Associate Professor of Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty