Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Rajaee 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)

Phone

+98 71 3230 5410

Email address

stud2301120899@sums.ac.ir

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 cholestrol

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- cholestrol

Timepoint
at baseline and at 12 weeks following end of intervention

Method of measurement
autoanalyzer bt1500

4

Description
LDL-cholestrol

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

Street address

Departmant of clinical Nutrition, School of Nutrition and Food Sciences, Razi Blvd, Modares Blvd, Shiraz

City

Shiraz

Postal code

Phone

+98 71 3725 1001

Fax

+98 71 3725 7288

Email

stud2301120899@suma.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nutrition and Food Sciences

Full name of responsible person

Mosa Salehi

Position

Associate Professor of Nutrition

Other areas of specialty/work

Street address

Departmant of Clinical Nutrition, School of Nutrition and Food Sciences, Razi Blvd, Modares Blvd, Shiraz

City

Shiraz

Postal code

Phone

+98 71 3725 1001

Fax

Email

salehi@sums.ac.ir

Web page address

Person responsible for updating data

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

Street address

Departmant of Clinical Nutrition, School of Nutrition and Food Sciences, Razi blvd, Modares Blvd, Shiraz

City

Shiraz

Postal code

Phone

+98 71 3725 1001

Fax

Email

Web page address

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