

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of the effects of Hibiscus sabdariffa on lipid profile, insulin resistance, oxidative stress, and hs-CRP level in adult patients with metabolic syndrome

Protocol summary

Summary

The purpose of this clinical trial to evaluate the effects of sour tea on metabolic syndrome Inclusion criteria:Patients with metabolic syndrome according to the criteria of panel The Adult Treatment Panel III (ATP III) treatment groups were 2005 adults.These criteria include having 3 of the 5 criteria: Abdominal obesity (waist circumference more 102 cm in men and than 88 cm In women);Decrease in plasma HDL-C (men less than 40 mg/dl and in women less than 50 mg/dl); Plasma hypertriglyceridemia (greater than 150 mg/dl); Hypertension (systolic blood pressure greater than or equal to 130 mm Hg or diastolic blood pressure greater than or equal to 85 mm Hg);And abnormal blood glucose (fasting blood glucose equal to or greater than 100). 40 patients with metabolic syndrome than 18 years will berandomly divided into two treatment groups and control. In the group of patients treated take a daily capsule of hibiscus tea after breakfast, for a month. At the beginning and end of a month of blood samples for determination of total cholesterol, HDL, LDL, TG, VLDL, Apo-A, Apo-B, FBS, insulin, hs-CRP and serum malondialdehyde (MDA). Also, BP and BMI were recorded and used to determine the possible effect of the drug on liver and renal function, serum urea and creatinine levels, as well as Cr and ALT and AST liver enzymes to be determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310089662N8**
Registration date: **2013-12-04, 1392/09/13**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-12-04, 1392/09/13

Registrant information

Name

Sedigheh Asgary

Name of organization / entity

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Cardiovascular Research institute , Physiology Re

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-11-21, 1392/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of Hibiscus sabdariffa on lipid profile, insulin resistance, oxidative stress, and hs-CRP level in adult patients with metabolic syndrome

Public title

Evaluation of the effects of sour tea on lipid profile,

insulin resistance, oxidative stress, and inflammatory markers in adult patients with metabolic syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Patients with metabolic syndrome according to the criteria of panel The Adult Treatment Panel III (ATP III) treatment groups were 2005 adults. These criteria include having 3 of the 5 criteria: Abdominal obesity (waist circumference more 102 cm in men and than 88 cm In women); Decrease in plasma HDL-C (men less than 40 mg/dl and in women less than 50 mg/dl); Plasma hypertriglyceridemia (greater than 150 mg/dl); Hypertension (systolic blood pressure greater than or equal to 130 mm Hg or diastolic blood pressure greater than or equal to 85 mm Hg); And abnormal blood glucose (fasting blood glucose equal to or greater than 100). exclusion criteria: People with diseases such as diabetes type 1 or 2; Thyroid disorders; nephrotic syndrome; Liver or kidney disease; Insulin, oral antidiabetic drugs; Drugs which affect blood lipid levels, such as statins; Oral contraceptive pills, hormones such as estrogen and progesterone; Smoking, alcohol and drugs; Pregnancy and lactation; drug allergy.

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Hezar jirib St. Isfahan Isfahan, Iran, Islamic Republic Of

City

Isfahan

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

391169

Health conditions studied

1

Description of health condition studied

metabolic syndrome

ICD-10 code

E78.8

ICD-10 code description

Other disorders of lipoprotein metabolism

Primary outcomes

1

Description

low-density lipoprotein (LDL)

Timepoint

Baseline and one month after intervention

Method of measurement

mg/dL - enzymatic - photometric

2

Description

Triglyceride (TG)

Timepoint

Baseline and one month after intervention

Method of measurement

mg/dL - enzymatic - photometric

3

Description

Total cholesterol (TC)

Timepoint

Baseline and one month after intervention

Method of measurement

mg/dL - enzymatic - photometric

4

Description

high-density Lipoprotein(HDL)

Timepoint

Baseline and one month after intervention

Method of measurement

mg/dL - enzymatic - photometric

5

Description

VLDL

Timepoint

Baseline and one month after intervention

Method of measurement

mg/dL - enzymatic - photometric

6

Description

Apo-A

Timepoint

Baseline and one month after intervention

Method of measurement

mg/dL - enzymatic - photometric

7

Description

Apo- B

Timepoint

Baseline and one month after intervention

Method of measurement

mg/dL - enzymatic - photometric

8

Description

Insulin

Timepoint

Baseline and one month after intervention

Method of measurement

mg/dL - enzymatic - photometric

9

Description

FBS

Timepoint

Baseline and one month after intervention

Method of measurement

mg/dL - enzymatic - photometric

10

Description

hs-CRP

Timepoint

Baseline and one month after intervention

Method of measurement

ng/dl/ Elisa

11

Description

MDA

Timepoint

Baseline and one month after intervention

Method of measurement

ng/dl/ Elisa

Secondary outcomes

1

Description

BMI

Timepoint

Baseline and one month after intervention

Method of measurement

W/M2

Intervention groups

1

Description

In group 1 capsule daily treatment will sour tea. Once a day after breakfast

Category

Treatment - Drugs

2

Description

In the control group taking placebo capsules daily, after breakfast

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Cardiovascular Research Center

Full name of responsible person

Mahtab Keshvari

Street address

Khorram Street, Jomhori Square

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr.Gholam Hossin Sadri

Street address

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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

Isfahan 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Isfahan Cardiovascular Research Center, Applied
Physiology Research Center, Isfahan University of Me

Full name of responsible person

Sedigheh Asgary

Position

Pharmacist and PhD Pharmacogenetics

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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*