Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Isfahan Cardiovascular Research Center ,Isfahan Cardiovascular Research institute , Physiology Re

Country

Iran (Islamic Republic of)

Phone

+98 31 1335 9090

Email address

s_asgari@crc.mui.ac.ir

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
Hezar jirib St.
City
Isfahan
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
Other areas of specialty/work
Street address
Khorram Street, Jomhoori Square
City
Isfahan
Postal code
Phone
+98 31 1335 9090
Fax
Email
sasgary@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Mohsen Zolghadr
Position
md Pharmacist
Other areas of specialty/work
Street address
Hezar jirib st.
City
Isfahan
Postal code
Phone
+98 31 1335 9090
Fax
Email
zolghadr.mohsen@yahoo.com
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