

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of alcoholic extract of hibiscus sabdariffa on lipid profiles, oxidative stress markers and hs-CRP in type 2 diabetic patients

Protocol summary

Summary

This study is carried out the effect of alcoholic Hibiscus tea extract on lipid profiles, markers of oxidative stress and inflammatory factors, hs-CRP in patients with type 2 diabetes in a randomized double-blind clinical trial in Research Center of Biochemistry and Nutrition in Metabolic Diseases, Medical University of Kashan. A total of 60 patients with type 2 diabetes selected with criteria and were randomized to either an intervention group (n = 30) and control (n = 30). After obtaining informed consent from the patient, a demographic, medical, and a 24-hour dietary recall (to determine energy and nutrient intake of patients) should be completed for each patient. Before the intervention, all patients were measured in fasting blood samples. During the study, the patients are advised not to alter their diet and activity. Because of this study is double-blind, the total package by someone other than the researcher and the patients are encoded. At the end of the study, blood samples will be collected again to measure variables .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212251576N2**

Registration date: **2012-12-29, 1391/10/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-12-29, 1391/10/09

Registrant information

Name

Ali Akbar Rshidi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1555 0021

Email address

rashidi@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences and Barij Essence CO.

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-07-23, 1392/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of alcoholic extract of hibiscus sabdariffa on lipid profiles, oxidative stress markers and hs-CRP in type 2 diabetic patients

Public title

Effect of alcoholic extract of hibiscus sabdariffa on lipids and inflammatory markers in type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: HbA1c < 8%; LDL < 130 mg/dl; TG < 300 mg/dl; no liver and kidney disease and no conception of lipid lowering drugs. Exclusion criteria: Hibiscus tea sensitivity; unwillingness to continue the study; insulin usage and change the dose of hypoglycemic drugs during the study.

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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**

Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, ghotb Ravandi
BLV, Kashan

City

Kashan

Postal code**Approval date**

2012-12-08, 1391/09/18

Ethics committee reference number

9188

Health conditions studied**1****Description of health condition studied**

Diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

Glucose

Timepoint

Before intervention and 3 months after intervention

Method of measurement

mg/dl

2**Description**

HbA1c

Timepoint

Before intervention and 3 months after intervention

Method of measurement

%

3**Description**

Total cholesterol

Timepoint

Before intervention and 3 months after intervention

Method of measurement

mg/dl

4**Description**

LDL and HDL cholesterol

Timepoint

Before intervention and 3 months after intervention

Method of measurement

mg/dl

5**Description**

Triglycerides

Timepoint

Before intervention and 3 months after intervention

Method of measurement

mg/dl

6**Description**

Total antioxidants

Timepoint

Before intervention and 3 months after intervention

Method of measurement

mmol/l

7**Description**

hs-CRP

Timepoint

Before intervention and 3 months after intervention

Method of measurement

ng/ml

Secondary outcomes

1

Description

ALT and AST

Timepoint

Before intervention and 3 months after intervention

Method of measurement

mg/dl

Intervention groups

1

Description

Control group received placebo (corn starch) 3 tablets daily for 3 months

Category

Placebo

2

Description

Intervention group: received 3 Hyporex-B tablets daily that contain alcoholic extract of Hibiscus sabdariffa for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Diabetes Center

Full name of responsible person

Street address

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research, Kashan University of Medical Sciences

Full name of responsible person

Somayyeh Nadi

Street address

Ghotb Ravandi BLV, Kashan University of Medical Sciences, Kashan.

City

kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor of Research, Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Ali Akbar Rashidi

Position

MSc in Nutrition

Other areas of specialty/work

Street address

Research Center for Biochemistry and Nutrition in Metabolic Diseases, Kashan University of Medical Sciences, Kashan.

City

Kashan

Postal code

Phone

+98 36 1555 0021

Fax

Email

rashidi@kaums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatola Asemi

Position

PhD in Nutrition

Other areas of specialty/work

Street address

Research Center for Biochemistry and Nutrition in Metabolic Diseases, Kashan University of Medical Sciences, Kashan

City

Kashan

Postal code

Phone

+98 36 1555 0021

Fax

Email

asemi@kaums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Ali Akbar Rashidi

Position

MSc in Nutrition

Other areas of specialty/work**Street address**

Research Center for Biochemistry and Nutrition in
Metabolic Diseases, Kashan University of Medical
Sciences

City

Kashan

Postal code**Phone**

+98 36 1555 0021

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