

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effect of saffron on fasting plasma glucose, HbA1c, Lipid profile, Insulin resistance, Homocystein levels, Antioxidant and Inflammatory biomarkers in patients with type 2

Protocol summary

Summary

This study is a prospective and randomized double-blind clinical trial. The aim of this study is effect of saffron on fasting plasma glucose, HbA1c, Lipid profile, Insulin resistance, Homocystein Levels, Antioxidant and Inflammatory biomarkers in patients with type 2 diabetes mellitus. Total of sample size is 76 patient with ages: 30-55 years old. The patients with hyperthyroidism and hypothyroidism, using insulin, using anticoagulants, diabetic nephropathy and pregnant and lactating women will be excluded. The patients are randomly divided into two groups by blocked randomization. Nurse drug distributor and patients do not know about the protocol of the study and type of drug. First group receives 15 milligram of saffron capsules once every 12 hours and twice in one day for 3 month. The second group as a control group receives placebo capsule once every 12 hours and twice in one day for 3 month. Both groups are matched in terms of taking energy, protein, fat and carbohydrates. Patients basic information such as age and sex, stature, BMI, serum triglyceride, LDL, HDL, total cholesterol, fasting blood sugar, fasting insulin levels, hemoglobin A1c (HbA1c), BUN/CR, liver enzymes (AST, ALT, ALK), inflammatory and immunological factors and homeostatic model assessment of β -cell function (HOMA- β %) and insulin resistance (HOMA-IR) will be recorded in both groups before intervention and after the intervention period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110219739N1**
Registration date: **2015-12-17, 1394/09/26**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-17, 1394/09/26

Registrant information

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Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-09-20, 1394/06/29

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of saffron on fasting plasma glucose, HbA1c, Lipid profile, Insulin resistance, Homocystein levels, Antioxidant and Inflammatory biomarkers in patients with type 2

Public title

The effect of saffron on treatment of diabetes mellitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with type 2 diabetes; Patients with ages: 30-55 years old; FBS levels between 126-200 milligrams per deciliter; HbA1c levels between 7% -8.5%.
Exclusion Criteria: Using insulin; Hyperthyroidism; Hypothyroidism; Allergy to saffron; Chronic complications of diabetes such as neuropathy and retinopathy; Smoking; Alcohol and drug abuse; Anticoagulant drugs such as macroalbuminuria in diabetic nephropathy; Renal failure; Pregnant and lactating women.

Age

From **30 years** old to **55 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

We want all patients continued their previous antidiabetic drugs and refrain from taking any other vitamin or mineral supplements during treatment and they are fasting the night before sampling for 8-12 hours.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Ahvaz Jundishapur University Of Medical Sciences

Street address

Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd., Ahvaz

City

Ahvaz

Postal code**Approval date**

2015-09-19, 1394/06/28

Ethics committee reference number

ir.ajums.REC.1394.350

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

Type 2 Diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

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

Fasting Blood Glucose

Timepoint

Before intervention and after completion of intervention in the twelfth week

Method of measurement

Venous sampling and sent to the laboratory

2**Description**

Hemoglobin A1c (HbA1c) levels

Timepoint

Before intervention and after completion of intervention in the twelfth week

Method of measurement

Venous sampling and sent to the laboratory

3**Description**

The serum levels of triglycerides, LDL, HDL, Total cholesterol

Timepoint

Before intervention and after completion of intervention in the twelfth week

Method of measurement

Venous sampling and sent to the laboratory

4**Description**

Fasting insulin levels

Timepoint

Before intervention and after completion of intervention in the twelfth week

Method of measurement

Venous sampling and sent to the laboratory

5**Description**

serum total antioxidants capacity

Timepoint

Before intervention and after completion of intervention in the twelfth week

Method of measurement

Venous sampling and sent to the laboratory

6

Description

The inflammatory markers

Timepoint

Before intervention and after completion of intervention in the twelfth week

Method of measurement

Venous sampling and sent to the laboratory

7

Description

body mass index (BMI)

Timepoint

Before intervention and after completion of intervention in the twelfth week

Method of measurement

By Using the formula: weight (kg) / the square of the height (m)

8

Description

insulin resistance

Timepoint

Before intervention and after completion of intervention in the twelfth week

Method of measurement

By Using the homeostasis model Assessment-insulin resistance (HOMA-ir) formula: fasting blood glucose (mmol/L) × fasting insulin (μU/ml)/22.5

9

Description

BUN/CR levels

Timepoint

Before intervention and after completion of intervention in the twelfth week

Method of measurement

Venous sampling and sent to the laboratory

10

Description

liver enzyme levels (AST, ALT, ALK)

Timepoint

Before intervention and after completion of intervention in the twelfth week

Method of measurement

Venous sampling and sent to the laboratory

Secondary outcomes

1

Description

Serum total cholesterol

Timepoint

before intervention and three months after intervention

Method of measurement

Laboratory kit

Intervention groups

1

Description

Group I (intervention group): Prescription 15 mg of saffron capsules once every 12 hours and twice in one day for 3 month. Each capsule contains 15 milligrams of dried extract of saffron, lactose, magnesium stearate and sodium starch glycolate.

Category

Treatment - Drugs

2

Description

Group II (control group): Prescription 15 mg of placebo capsule once every 12 hours and twice in one day for 3 month. Each capsule contains lactose, magnesium stearate and sodium starch glycolate.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Armaghan Moravej Aleali

Street address

Golestan Hospital, Farvardin St., Golestan, Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Nader Saki

Street address

Vice chancellor For Research Of Ahvaz Jondishapour University of Medical Sciences, Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

City

Ahvaz

Grant name

-

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor For Research Of Ahvaz Jundishapur

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

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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