Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Name

Armaghan Moravej Aleali

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Iran (Islamic Republic of)

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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
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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

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Armaghan Moravej Aleali

Position

PhD Student By Research

Other areas of specialty/work

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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