Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Effect of Saffron consumption in comparison with placebo on Glycemic status, lipid profile, nephropathy, fat body percent and some blood biochemical parameters in type 2 Diabetic Patients

Protocol summary

Summary

Objective: This study examined the effect of Saffron consumption in comparison with placebo on Glycemic status, lipid profile, nephropathy, fat body percent and some blood biochemical parameters in type 2 Diabetic Patients. Design of study: Randomized, double blind, placebo controlled, single center and phase 2-3 trial.The patients, executive researcher and the chief colleague will not aware of allocation of patients to intervention and control groups. Setting and conduct: 90 diabetic Patients according to specialist diagnosis from clinics of Iran University of Medical Sciences will be enrolled.They will be divided in 2 groups based on random numbers table; Intervention group and placebo group. Intervention group will receive one pill of Saffron and placebo group will receive placebo pill. Participants inclusion and major eligibility criteria: Type 2 Diabetic adults with completed informed consent form and 30-70 years ages will be included in the study. Major exclusion criteria: Insulin consumption, reluctance for continuing the cooperation, taking less than 80% of supplements given to patients at baseline(the compliance lower than 80%) will be excluded participants from study. Intervention groups: patients in case group will receive one Pill containing 100 mg Powder of Saffron daily with meal and placebo patients will receive one pill containing 100 mg Maltodextrin daily with meal for 3 months. Before and after the 3 months intervention periods, glycemic index(HbA1c, FBS, Insulin), lipid profile(HDL-C, TG, LDL-C, TC)and biochemical criteria including Inflammatory indices(TNF-a, hs-CRP), Total antioxidant capacity, Indicator of oxidative stress(MDA) And nephropathy indices(albuminuria , BUN, Cr), liver enzymes(ALT,AST) in two groups will be compared. Waist circumference and BMI, body fat percent, blood pressure will be assessed too. For Dietary assessment of patients and control potential confounding factors of diet, 3-day dietary recall questionnaire and physical activity questionnaire(IPAQ) will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510259472N9**
Registration date: **2015-12-12, 1394/09/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-12, 1394/09/21

Registrant information

Name
Naheed Aryaeian
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8670 4750
Email address
aryaeian.n@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Saffron consumption in comparison with placebo on Glycemic status, lipid profile, nephropathy, fat body percent and some blood biochemical parameters in type 2 Diabetic Patients

Public title

Effect of Saffron consumption in type 2 Diabetic Patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients with type 2 Diabetes; 30-70 years ages; diabetes patients with oral medication intake; not Smoking and Alcohol intake; Hb A1C: 7-10 % ; BMI between 20-35; no Pregnancy and Lactation; not consumption of antioxidants , multivitamins and omega 3 supplements from 3 months ago; do not taking the lipid and blood pressure- lowering drugs ; not consumption contraceptives and insulin therapy.
Exclusion criteria: unwillingness to continue cooperation; taking less than 80% of supplements(the compliance lower than %80); changes in Diet or Physical activity; changes in type or dose of medication; renal, hepatic, thyroid and Parathyroid disorders.

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences , The intersection of Sheikh Fazlallah and Shahid Chamran, Shahid Hemman highway

City

Tehran

Postal code

Approval date

2015-10-25, 1394/08/03

Ethics committee reference number

IR.IUMS.REC.1394.26583

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E10

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

HbA1c

Timepoint

Before intervention and three months after intervention

Method of measurement

ELISA

2

Description

FBS

Timepoint

Before intervention and three months after intervention

Method of measurement

Enzymatic method

3

Description

Insulin

Timepoint

Before intervention and three months after intervention

Method of measurement

ELISA

4

Description

Total cholesterol

Timepoint

Before intervention and three months after intervention

Method of measurement

Enzymatic method

5

Description
Triglyceride
Timepoint
Before intervention and three months after intervention
Method of measurement
Enzymatic method

6

Description
LDL
Timepoint
Before intervention and three months after intervention
Method of measurement
Enzymatic method

7

Description
HDL
Timepoint
Before intervention and three months after intervention
Method of measurement
Enzymatic method

8

Description
Systolic blood pressure
Timepoint
Before intervention and three months after intervention
Method of measurement
Mercury sphygmomanometer

9

Description
Diastolic blood pressure
Timepoint
Before intervention and three months after intervention
Method of measurement
Mercury sphygmomanometer

10

Description
MDA(Malondialdehyde)
Timepoint
Before intervention and three months after intervention
Method of measurement
Spectrophotometry method

11

Description
hs-CRP
Timepoint
Before intervention and three months after intervention
Method of measurement
ELISA

12

Description
TNF-a
Timepoint
Before intervention and three months after intervention
Method of measurement
ELISA

13

Description
TAC(Total antioxidant capacity)
Timepoint
Before intervention and three months after intervention
Method of measurement
Spectrophotometry method

14

Description
BMI(Body mass index)
Timepoint
Before intervention and three months after intervention
Method of measurement
Weight (kg)/[height (m)]2, kg/m2

15

Description
Age
Timepoint
Before intervention
Method of measurement
questionnaire

16

Description
Weight
Timepoint
Before intervention and three months after intervention
Method of measurement
Scale

17

Description
Sex
Timepoint
Before intervention
Method of measurement
questionnaire

18

Description
Height
Timepoint
Before intervention
Method of measurement
Standard scales Seca

19

Description
Fat body percent
Timepoint
Before intervention and three months after intervention
Method of measurement
view/ body composition analyzer

20

Description
Waist circumference
Timepoint
Before intervention and three months after intervention
Method of measurement
Tape measure

21

Description
Macronutrients intake (Energy ,carbohydrates ,protein ,types of lipid ,fiber)
Timepoint
Before intervention and three months after intervention
Method of measurement
24 hour Food questionnaire

22

Description
Micronutrient intake (vit C, A , Beta carotene ,zn ,se,cu,Na , K , Mg ,saffron)
Timepoint
Before intervention and three months after intervention
Method of measurement
24 hour Food questionnaire

23

Description
physical activity level
Timepoint
Before intervention and three months after intervention
Method of measurement
questionnaire

24

Description
BUN
Timepoint
Before intervention and three months after intervention
Method of measurement
Autoanalyzer

25

Description
Cr
Timepoint
Before intervention and three months after intervention
Method of measurement
Autoanalyzer

26

Description
Albumin
Timepoint
Before intervention and three months after intervention
Method of measurement
Autoanalyzer

27

Description
liver enzymes(AST ,ALT)
Timepoint
Before intervention and three months after intervention
Method of measurement
photometric assay

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: receiving one pill containing 100 mg powder of Saffron daily with meal for 3 months.
Category
Treatment - Drugs

2

Description
Control group: receiving one pill containing 100 mg maltodextrin daily with meal for 3 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran University of Medical Sciences
Full name of responsible person
Fatemeh Ebrahimi
Street address
School of Public Health,Iran University of Medical Sciences,The intersection Sheikh Fazlallah and Shahid Chamran,Shahid Hemmat highway
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Vice-chancellor for research Iran University of Medical Sciences

Full name of responsible person

Dr Ali Javad Moosavi,Assistant of Research and Technology,Iran University of Medical Sciences

Street address

Iran University of Medical Sciences,The intersection of Sheikh Fazlallah and Shahid Chamran,Shahid Hemmat highway

City

Tehran

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 Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr Nahid Aryaeian

Position

Phd in Nutrition

Other areas of specialty/work

Street address

School of health, Iran University of Medical Sciences, the intersection of Sheikh Fazlallah and Chamran, Shahid Hemmat highway

City

Tehran

Postal code

Phone

+98 21 8877 9118

Fax

Email

n-aryaeian@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Naheed Aryaeian

Position

Professor Assistant / Nutrition PhD.

Other areas of specialty/work

Street address

School of health, Iran University of Medical Sciences,The intersection of Sheikh Fazlallah and Shahid Chamran, Shahid Hemmat highway

City

Tehran

Postal code

Phone

+98 21 8877 9118

Fax

Email

n-aryaeian@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Fatemeh Ebrahimi

Position

MS Student in Nutrition

Other areas of specialty/work

Street address

Faculty of Nutrition, School of health ,Iran University of Medical Sciences,The intersection of Sheikh Fazlallah and Shahid Chamran, Shahid Hemmat highway

City

Tehran

Postal code

Phone

00

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