# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 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
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Iran (Islamic Republic of)
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**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**

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**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**

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**Full name of responsible person**

Dr Nahid Aryaeian

**Position**

Phd in Nutrition

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Full name of responsible person**

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**Other areas of specialty/work**

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

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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*