

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### The effect of saffron tablet on lipid profiles and blood glucose and oxidative stress in obese prediabetic patients

#### Protocol summary

##### Study aim

The aim of this study is to evaluate the effect of saffron pill on lipid profiles and blood glucose and oxidative stress in obese diabetic patients

##### Design

In this research, 80 pre-diabet patients referring to Emam Ali clinic were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

##### Settings and conduct

A randomized clinical trial was conducted on pre-diabetes patients referring to Imam Ali Clinic, Also, the participants were blinded by this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: all patients with BMI greater than 25 who referring to the Imam Ali nutrition clinic, which are defined as pre-diabetes Exclusion criteria: :Lack of interest in cooperation- Pregnancy- change in diet or physical activity- change in dosage and type of drug- Not having other diseases in during the study- Do not use more than 30% pills

##### Intervention groups

saffron receiving group placebo receiving group

##### Main outcome variables

Fasting blood glucose Oral glucose tolerance test hemoglobin A1C

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120913010826N19**

Registration date: **2018-01-04, 1396/10/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-01-04, 1396/10/14**

Update count: **1**

##### Registration date

2018-01-04, 1396/10/14

##### Registrant information

###### Name

Azadeh Nadjarzadeh

###### Name of organization / entity

Shahid Sadoughi University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 912 202 2817

###### Email address

azadnajarzadeh@ssu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

shahid sadoughi university of medical sciences

##### Expected recruitment start date

2017-11-01, 1396/08/10

##### Expected recruitment end date

2018-01-30, 1396/11/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of saffron tablet on lipid profiles and blood glucose and oxidative stress in obese prediabetic patients

##### Public title

The effect of saffron tablet in obese prediabetic patients

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

all patients which are defined as pre-diabetes who referring to the Imam Ali nutrition clinic all patients with BMI greater than 25 who referring to the Imam Ali nutrition clinic

**Exclusion criteria:**

Pregnancy change in diet or physical activity change in dosage change in type of drug Lack of interest in cooperation having other diseases in during the study Do not use more than 30% pills

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**

Target sample size: 80

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization will be done using www.randomization.com to assign equal participants in each group (1:1 allocation ). An independent researcher will make random allocation cards using computer-generated random numbers. he will keep the original random allocation sequences until analysis time. Another independent researcher will measure the patients outcome and she will not know the allocation.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

dietary supplements and placebo produced and coded in similar shape, color, and size by the company. Allocation concealment will be done using sealed envelopes. So, principal researcher, clinician, and participants are not aware about group assignment.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Shahid Sadoughi University of Medical Sciences

**Street address**

Campus of Sadoughi University of Medical Sciences,

Shohadaye Gomnam Blv,Yazd

**City**

Yazd

**Province**

Yazd

**Postal code**

8915173160

**Approval date**

2016-03-05, 1394/12/15

**Ethics committee reference number**

IR.SSU.SPH.REC.1394.113

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

Obese Pre-dabetic

**ICD-10 code**

R73.02

**ICD-10 code description**

Impaired glucose tolerance (oral)

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

LDL (lipid profile index)

**Timepoint**

Before and after intervention

**Method of measurement**

Standards of medical diagnostic laboratories

**2****Description**

TG (lipid profile index)

**Timepoint**

Before and after intervention

**Method of measurement**

Standards of medical diagnostic laboratories

**3****Description**

cholesterol(lipid profile index)

**Timepoint**

Before and after intervention

**Method of measurement**

Standards of medical diagnostic laboratories

**Secondary outcomes****1****Description**

triglyceride, , LDL-Chol, BUN, Creatinine, DPPH

**Timepoint**

before and after intervention

**Method of measurement**

Standards of medical diagnostic laboratories

## 2

### **Description**

cholesterol

### **Timepoint**

before and after intervention

### **Method of measurement**

Standards of medical diagnostic laboratories

## 3

### **Description**

LDL cholesterol concentration

### **Timepoint**

before and after intervention

### **Method of measurement**

Standards of medical diagnostic laboratories

## 4

### **Description**

BUN

### **Timepoint**

before and after intervention

### **Method of measurement**

Standards of medical diagnostic laboratories

## 5

### **Description**

creatinine

### **Timepoint**

before and after intervention

### **Method of measurement**

Standards of medical diagnostic laboratories

## 6

### **Description**

DPPH

### **Timepoint**

before and after intervention

### **Method of measurement**

Standards of medical diagnostic laboratories

## **Intervention groups**

### 1

#### **Description**

The control group will receive placebo (the same as saffron pill in doses of 15mg)once a day for 8 weeks

#### **Category**

Placebo

### 2

#### **Description**

The intervention group will receive saffron pill in dosage 15 mg ,once a day (for 8 weeks)

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam Ali clinic

##### **Full name of responsible person**

Azadeh Nadjarzadeh

##### **Street address**

Navvab Safavi Blvd, Yazd

##### **City**

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##### **Phone**

+98 35 3149 2239

##### **Email**

azadehnajarzadeh@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Yazd University of Medical Sciences

##### **Full name of responsible person**

Dr. Amir Hoshangh Mehrparvar

##### **Street address**

Sadoughi University of Medical Sciences, shahid bahonar sq,Yazd

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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**

Yazd University of Medical Sciences

##### **Proportion provided by this source**

100

##### **Public or private sector**

Public

##### **Domestic or foreign origin**

Domestic

##### **Category of foreign source of funding**

*empty*

##### **Country of origin**

##### **Type of organization providing the funding**

Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

shahid sadoughi university of medical sciences

**Full name of responsible person**

Dr.Azadeh Nadjarzadeh

**Position**

Associate Professor, nutrition specialist

**Latest degree**

Ph.D.

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

department of nutrition, school of public health,shahid sadoughi university of medical sciences, Yazd, Iran

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Associate Professor, nutrition specialist

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Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Email**

azadehnajarzadeh@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

data report will be shared after publishing the paper.

**When the data will become available and for how long**

Six months after publish

**To whom data/document is available**

Academic researchers

**Under which criteria data/document could be used**

Using for Meta-analysis

**From where data/document is obtainable**

Center nutrition, public health, univercity of medical scienices yazd Tel: 009835 31492239 Email: azadehnajarzadeh@gmail.com Azadenadjarzadeh

**What processes are involved for a request to access data/document**

It will be sent two weeks after the receipt of the email with the consent of the co-workers

## Comments