

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Yazd

Province

Yazd

Postal code

8915173160

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

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3149 2239

Email

azadehnajarzadeh@gmail.com

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

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3149 2239

Fax**Email**

azadnajarzadeh@ssu.ac.ir

Web page address

Person responsible for scientific 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

Nutrition

Street address

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

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3149 2239

Fax**Email**

azadnajarzadeh@ssu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Azadeh Najarzadeh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Shahid Sadoughi University of Medical Sciences, Yazd, Alam Square, Shohadaye Gomnam Street

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3149 2239

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, university of medical sciences 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