

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Association between saffron supplementation and metabolic factors, serum oxidative stress indices and gene expression rate of pyroptosis related inflammatory factors in patients with type 2 diabetes

Protocol summary

Study aim

Association between saffron supplementation and metabolic factors, serum oxidative stress indices and gene expression rate of pyroptosis related inflammatory factors in patients with type 2 diabetes

Design

This is a parallel, randomized, double-blind, placebo-controlled clinical trial. 60 Subjects with type 2 diabetes matched with inclusion criteria will recruit from the Clinic of Tabriz University of Medical Sciences, Tabriz, Iran. The patients will randomly assign to two groups, intervention group and control group and a code was allocated to each one of them.

Settings and conduct

The informed consent will obtain from participants before interview. A structured questionnaire for all the participants by face-to-face interview will completed to collect information on demographics, 24 hr food recall and physical activity level. Anthropocentric indices (weight, BMI, waist circumference, hip circumference and WHR) will measure. The patients will randomly assign to two groups, intervention group receiving 100 mg saffron powder per day and control group consumed 100 mg of starch and dextrose per day for 8 weeks. For biochemical measurements, 10 ml venous blood samples were gathered after 12-hour overnight fasting. Statistical analysis will perform using SPSS version 13 (spssInc, Chicago, IL, USA). This study will be blind from patients and researcher.

Participants/Inclusion and exclusion criteria

Inclusion criteria: subjects with T2D, aged 20-60 years, BMI 25-35 kg/m², not on insulin therapy. Exclusion criteria: pregnancy or lactation, subjects needed to start insulin therapy during intervention, suffering from chronic inflammatory disorders, renal or hepatic disease, smoking, any change in type or dosage of drugs, in diet or physical activity during the running period, consuming

NSAIDs, steroids or hormonal drugs

Intervention groups

The 60 diabetic patients will randomly assign to two groups, intervention group receiving 100 mg saffron powder per day and control group consumed 100 mg of starch and dextrose per day for 8 weeks.

Main outcome variables

Expression rate of TLR-4, NLRP3, TXNIP, Caspase-1, IL-1 β , IL-18; Serum level of Glucose, HbA1c, Insulin, Insulin resistance and lipid profile (TG, TC, LDL, HDL); Systolic and diastolic blood pressure, anthropocentric indices (weight, BMI, waist circumference, hip circumference and WHR); Total antioxidant capacity, antioxidant enzymes (superoxide dismutase, glutathione peroxidase, catalase) and pro-oxidants (MDA, NO)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090609002017N24**

Registration date: **2017-12-21, 1396/09/30**

Registration timing: **prospective**

Last update: **2017-12-21, 1396/09/30**

Update count: **0**

Registration date

2017-12-21, 1396/09/30

Registrant information

Name

Alireza Ostadrahimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address	ostadrahimi@tbzmed.ac.ir	Blinding (investigator's opinion)	Double blinded
Recruitment status	Recruitment complete	Blinding description	This is a double-blind study and both of the patients and researcher will be blind to group allocation.
Funding source	Nutritional Research Center	Placebo	Used
Expected recruitment start date	2017-12-22, 1396/10/01	Assignment	Parallel
Expected recruitment end date	2018-02-20, 1396/12/01	Other design features	
Actual recruitment start date	empty	Secondary Ids	empty
Actual recruitment end date	empty	Ethics committees	
Trial completion date	empty	1	
Scientific title	Association between saffron supplementation and metabolic factors, serum oxidative stress indices and gene expression rate of pyroptosis related inflammatory factors in patients with type 2 diabetes	Ethics committee	
Public title	Saffron effect on pancreatic beta cell pyroptosis in patients with type 2 diabetes	Name of ethics committee	کمیته اخلاق دانشگاه علوم پزشکی تبریز
Purpose	Treatment	Street address	Attar Neishaburi Ave, Golgasht Ave, Tabriz University of Medical Sciences
Inclusion/Exclusion criteria		City	تبریز
Inclusion criteria:	Tendency to attend in study Subjects with T2D Males and females aged 20-60 years BMI 25-35 kg/m2 Not on insulin therapy	Province	East Azarbaijan
Exclusion criteria:	Not tendency to attend in study Suffering from chronic inflammatory disorders, renal or hepatic disease Consuming NSAIDs, steroids or hormonal drugs Any change in type or dosage of drugs Any change in diet or physical activity during the running period Smoking Subjects needed to start insulin therapy during intervention Pregnancy or lactation	Postal code	5157743856
Age	From 30 years old to 60 years old	Approval date	2017-12-04, 1396/09/13
Gender	Both	Ethics committee reference number	IR.TBZMED.REC.1396.808
Phase	N/A	Health conditions studied	
Groups that have been masked	- Participant - Investigator	1	
Sample size	Target sample size: 60	Description of health condition studied	Type 2 diabetes
Randomization (investigator's opinion)	Randomized	ICD-10 code	E11
Randomization description	Simple randomization will be used for each person by random numbers. due to proper allocation concealment, trial investigators and participants will be unaware of upcoming allocations.	ICD-10 code description	Non-insulin dependent diabetes
		Primary outcomes	
		1	
		Description	expression rate of TLR-4
		Timepoint	before and 2 months after the intervention
		Method of measurement	RT-PCR
		2	
		Description	expression rate of NLRP3

Timepoint
before and 2 months after the intervention
Method of measurement
RT-PCR

3

Description
expression rate of TXNIP
Timepoint
before and 2 months after the intervention
Method of measurement
RT-PCR

4

Description
expression rate of Caspase-1
Timepoint
before and 2 months after the intervention
Method of measurement
RT-PCR

5

Description
expression rate of IL-1 β
Timepoint
before and 2 months after the intervention
Method of measurement
RT-PCR

6

Description
expression rate of IL-18
Timepoint
before and 2 months after the intervention
Method of measurement
RT-PCR

7

Description
Fasting Blood Glucose
Timepoint
before and 2 months after the intervention
Method of measurement
Enzymatic glucose oxidase method

8

Description
HOMA-IR
Timepoint
before and 2 months after the intervention
Method of measurement
Estimation base on formula

9

Description
Insulin
Timepoint

before and 2 months after the intervention
Method of measurement
ELISA Kit

10

Description
HbA1c
Timepoint
before and 2 months after the intervention
Method of measurement
Spectrophotometry

11

Description
Malon Dialdehyde
Timepoint
before and 2 months after the intervention
Method of measurement
Spectrophotometry

12

Description
Nitric Oxide
Timepoint
before and 2 months after the intervention
Method of measurement
Spectrophotometry

13

Description
Total Antioxidan Capacity
Timepoint
before and 2 months after the intervention
Method of measurement
kit

14

Description
Catalase
Timepoint
before and 2 months after the intervention
Method of measurement
kit

15

Description
Super Oxide Dismutase
Timepoint
before and 2 months after the intervention
Method of measurement
kit

16

Description
Glutathion Peroxidase
Timepoint
before and 2 months after the intervention

Method of measurement

kit

17**Description**

Triglyceride

Timepoint

before and 2 months after the intervention

Method of measurement

Enzymatic method

18**Description**

HDL-Colesterol

Timepoint

before and 2 months after the intervention

Method of measurement

Enzymatic method

19**Description**

Total Cholesterol

Timepoint

before and 2 months after the intervention

Method of measurement

Enzymatic method

20**Description**

LDL-Cholesterol

Timepoint

before and 2 months after the intervention

Method of measurement

Estimation base on formula

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

Weight

Timepoint

before, 1 month and 2 months after the intervention

Method of measurement

Scale

2**Description**

Energy and Macro-nutrient intake

Timepoint

before, 1 month and 2 months after the intervention

Method of measurement

Questionnaire

3**Description**

Body Mass Index

Timepoint

before, 1 month and 2 months after the intervention

Method of measurement

Estimation

4**Description**

Waist Circumference

Timepoint

before, 1 month and 2 months after the intervention

Method of measurement

mounted tape

5**Description**

Hip Circumferences

Timepoint

before, 1 month and 2 months after the intervention

Method of measurement

mounted tape

6**Description**

Waist to Hip Ratio

Timepoint

before, 1 month and 2 months after the intervention

Method of measurement

Estimation

7**Description**

Systolic Blood Pressure

Timepoint

before, 1 month and 2 months after the intervention

Method of measurement

digital system

8**Description**

Diastolic Blood Pressure

Timepoint

before, 1 month and 2 months after the intervention

Method of measurement

digital system

9**Description**

Physical activity level

Timepoint

before, 1 month and 2 months after the intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Saffron powder, 50 mg capsule, 2 per day, for 2 months

Category

Treatment - Drugs

2

Description

Starch and dextrose powder, 50 mg capsule, 2 per day, for 2 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

The Clinic of Tabriz University of Medical University

Full name of responsible person

Aynaz Seyed Tajaddini

Street address

Attar Neishaburi Ave, Golgasht Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nutritional Research Center

Full name of responsible person

Doustzadeh

Street address

Nutrition Faculty, Tabriz University of Medical Sciences, Attar Neishaburi Ave, Golgasht Ave

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Email

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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

Nutritional Research Center

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

Tabriz University of Medical Sciences

Full name of responsible person

Aynaz Seyed Tajaddini

Position

PhD student of Nutrition

Latest degree

Master

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

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City
Tabriz
Province

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

All data are resulting from dissertation and will be used just for manuscript printing in academic journals.

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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available