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-1β, 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)

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Recruitment status
Recruitment complete
Funding source
Nutritional Research Center

Expected recruitment start date
2017-12-22, 1396/10/01
Expected recruitment end date
2018-02-20, 1396/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

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

Public title
Saffron effect on pancreatic beta cell pyroptosis in patients with type 2 diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
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
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
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
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.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double-blind study and both of the patients and researcher will be blind to group allocation.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی تبریز
Street address
Attar Neishaburi Ave, Golgasht Ave, Tabriz University of Medical Sciences
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Postal code
5157743856
Approval date
2017-12-04, 1396/09/13
Ethics committee reference number
IR.TBZMED.REC.1396.808

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E11
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-1β
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
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Attar Neishaburi Ave, Golgasht Ave
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Email
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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
Tajaddinia@gmail.com
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
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Person responsible for updating data

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tajaddinia@gmail.com
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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