Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical Trial comparing the effect of alcoholic extract of saffron (Crocus satious L.) and placebo in the treatment of mild to moderate mixed depression - anxiety and related metabolic parameters in type 2 diabetes mellitus

Protocol summary

Summary

This study will conduct at diabetes society of Natanz. All of the registered diabetes patients in the society will invite for depression and anxiety screening by telephone. Beck depression inventory and Beck anxiety inventory will write from the patients. the patients will select according to these criteria: Beck depression scores higher than 10 as depression, Beck anxiety scores higher than 8 as anxiety. Then,the patients will assess with DSM-IV by a psychologist to conclusive diagnosis. patients with both depression and anxiety will write Hamilton depression and anxiety questionnaires to determine depression and anxiety severity.patients with 14 to 24 scores at the anxiety questionnaire and 15 to 39 scores at the depression questionnaire will assume as suffer from mild to moderate anxiety and depression and will select according to inclusion criteria. Fifty four patients will select randomly among them. The selected patients will invite to central laboratory of Natanz. Fasting blood sugar, 2hour plasma glucose, Hemoglobin A1C and lipid profiles including triglyceride, HDL, and total cholesterol will calculate. LDL will calculate by Friedwalds' formula. ALT, AST, ALP and BUN, Creatinine and uric acid will also measure. Height and weight of the patient will measure at the same day. Then, 54 patients randomly assign to intake saffron or placebo capsules. Of the patients, 27 patients intake 15 mg saffron capsules twice a day (30 mg/day) and 27 patients intake 15 mg placebo capsules (30 mg/day) for 8-weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082623776N1**

Registration date: **2015-12-10, 1394/09/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-10, 1394/09/19

Registrant information

Name

Abolghassem Djazayeri

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 9118

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial comparing the effect of alcoholic extract of saffron (Crocus satious L.) and placebo in the treatment

of mild to moderate mixed depression - anxiety and related metabolic parameters in type 2 diabetes mellitus

Public title
Effect of Saffron on depression and anxiety
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria were: type 2 diabetes mellitus; 40 to 65 years old; mild to moderate anxiety and depression; fasting blood glucose under 170 mg/dl; Body Mass Index (BMI) between 18.5 to 40 kg/m2. Exclusion criteria were: less than 40 and more than 65 years old; mental related drugs (such as anti-depression and anti-anxiety drugs) using; severe depression and anxiety; tobacco or opium using; insulin using; uncontrolled blood glucose; severe physical activity; severe stress at the near past; emotional defeat at the near past; hospitalization at the near past; pregnancy or lactating or patients programmed for pregnancy; other diseases than depression and anxiety; mental disorders in the first degree relatives; BMI less than 18.5 or more than 40 kg/m2.
Age
From **54 years** old to **29 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Enghelab St
City
Tehran
Postal code
Approval date
2015-04-15, 1394/01/26
Ethics committee reference number
ir.tums.rec.1394.9211468004-143703

Health conditions studied

1

Description of health condition studied
mixed depression and anxiety, type 2 diabetes
ICD-10 code
E11 , F38.
ICD-10 code description
Non-insulin-dependent diabetes mellitus, Other single mood [affective] disorders

Primary outcomes

1

Description
Beck depression score
Timepoint
8 weeks
Method of measurement
Beck questionnaire

2

Description
Beck anxiety
Timepoint
8 weeks
Method of measurement
Beck questionnaire

3

Description
Hamilton depression score
Timepoint
8 weeks
Method of measurement
Hamilton questionnaire

4

Description
Hamilton anxiety score
Timepoint
8 weeks
Method of measurement
Hamilton questionnaire

Secondary outcomes

1

Description
Placebo and saffron capcules side effects
Timepoint
8 weeks

Method of measurement
Ask from the patients during periodical examinations

2

Description
Hemoglobin A1C
Timepoint
8 weeks
Method of measurement
Blood examination

3

Description
Fasting blood sugar
Timepoint
8 weeks
Method of measurement
Blood examination

4

Description
2 Hour blood glucose
Timepoint
8 weeks
Method of measurement
Blood examination

5

Description
Alanine amino teransferase
Timepoint
8 weeks
Method of measurement
Blood examination

6

Description
Aspartate amino teransferase
Timepoint
8 weeks
Method of measurement
Blood examination

7

Description
Alkaline phosphatase
Timepoint
8 weeks
Method of measurement
Blood examination

8

Description
Creatinine
Timepoint
8 weeks
Method of measurement
Blood examination

9

Description
Blood urea nitrogen
Timepoint
8 weeks
Method of measurement
Blood examination

10

Description
Uric acid
Timepoint
8 weeks
Method of measurement
Blood examination

11

Description
low density lipoprotein
Timepoint
8 weeks
Method of measurement
Blood examination

12

Description
High density lipoprotein
Timepoint
8 weeks
Method of measurement
Blood examination

13

Description
Trigelyceride
Timepoint
8 weeks
Method of measurement
Blood examination

Intervention groups

1

Description
saffron group patients treat with 15 mg saffron extract capsules twice a day (30 mg per day) for 8 weeks. the patients will recruit to not change their physical activity and diet during the intervention. Placebo capsules contain starch, lactose, magnesium stearate, gelatin, and saffron extract.
Category
Treatment - Drugs

2

Description
Placebo group patients intake placebo capsules 15 mg twice a day (30 mg daily) for 8 weeks. The patients will recruit to not change their diet and physical activity during the study. Placebo capsules contain starch, lactose, magnesium stearate, gelatin, and saffron essence.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Natanz diabetes society
Full name of responsible person
Alireza Milajerdi
Street address
No.3, 32 Dastgah
City
Natanz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Neda Mohammad Nezhad
Street address
College of nutrition, hojjat doost st
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran university of medical sciences
Full name of responsible person
Abolgassem Djazayeri
Position
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Person responsible for scientific inquiries

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Person responsible for updating data

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amkhv@yahoo.com
Web page address

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