Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of adding saffron to fluoxetine in the treatment of mild to moderate depression in type 2 diabetes mellitus patients: A Randomized Double-Blinded Study

Protocol summary

Study aim
The effect of adding saffron to fluoxetine in the treatment of mild to moderate depression in type 2 diabetes mellitus patients

Design
This is a clinical trial study with parallel groups, double-blinded randomized, phase 3. Allocation of patients to the study groups will be done by random numbers generation and using computer by excel software

Settings and conduct
This study will be performed on 60 patients with type 2 diabetes mellitus with a diagnosis of mild to moderate depression in Imam Khomeini hospital, Ahvaz. The patients will be randomly assigned to one of two treatment groups. The patients and experimenters will not know about type of treatment and patient grouping and thus until the end of trial the study will be remained double-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18-60 years, diabetes mellitus type 2, mild to moderate depression, consent to participate in the study; Exclusion criteria: Consumption of psychiatric drugs before the study, substance abuse, insulin consumption, uncontrolled diabetes, history of severe stress, pregnancy, lactation, other psychiatric illnesses including anxiety disorders, Previous history of depression, Mental disability.

Intervention groups
Intervention group: Fluoxetine 10 mg, once a day (Abidi Pharmaceutical Company, Iran) will be prescribed for 4 weeks and then the patients will be received Deprofade saffron capsule 20 mg per day (Tolou Gostar Bokhara Company, Iran) along with fluoxetine 10 mg for 4 weeks. Control group: Fluoxetine 10 mg will be prescribed for 4 weeks and then patients will be received a similar capsule containing placebo (prepared in the Faculty of Pharmacy of Ahvaz Jundishapur University) along with fluoxetine for 4 weeks.

Main outcome variables
The severity of depression and incidence of treatment-related complication

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220309054235N1**
Registration date: **2022-03-27, 1401/01/07**
Registration timing: **prospective**

Last update: **2022-03-27, 1401/01/07**
Update count: **0**

Registration date
2022-03-27, 1401/01/07

Registrant information

Name
Masumeh Ebrahimilagha

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 933 312 7369

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-21, 1401/02/01

Expected recruitment end date
2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding saffron to fluoxetine in the treatment of mild to moderate depression in type 2 diabetes mellitus patients: A Randomized Double-Blinded Study

Public title

Effect of saffron in treatment of depression in diabetes patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-60 years Diabetes mellitus type 2 Mild to moderate depression Fasting blood sugar less than 170 mg/dl Body mass index between 18.5 to 40 Consent to participate in the study

Exclusion criteria:

Consumption of psychiatric drugs before the study Substance abuse Insulin consumption Uncontrolled diabetes (HbA1c above 8%) History of severe stress Pregnancy Lactation other psychiatric illnesses including anxiety disorders Previous history of depression Mental disability

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned into two groups by simple randomization method. Allocation of patients to the study groups will be done by random numbers generation and using computer by excel software. Random numbers will be generated in Excel with RAND function [(=RAND()*(60)] and with this function 60 random numbers will be created in the range of 1 to 60 in a column. Each patient will be assigned a two-digit code from 01 to 60. From the beginning of the first row, move down the column of random numbers and check the first two digits of the random numbers. The first 30 people seen in our code range will be placed in the first group (intervention) and the second 30 people will place in the second group (control). A person from hospital staff, who will not responsible for patient selection, enrollment, or treatment allocation, performs the randomization. The patients will be included in one of the two treatment groups before starting treatment. The implementation of the random allocation sequence occurs without knowledge of which patient will receive which treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, physicians, nurses, data collectors, those assessing the consequences, and the Safety and Data Monitoring Committee will be kept blind. In order to eliminate the bias caused by the knowledge of them, the results are based on the type of treatment received and its possible impact on the research result of the study in a double-blind manner. The appearance of the placebo will be similar to that of saffron capsule. Also patients and statistical analyzer will not know about patient grouping.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Approval date

2021-11-09, 1400/08/18

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1400.176

Health conditions studied

1

Description of health condition studied

Mild to moderate depression

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description
The severity of depression
Timepoint
Before and after intervention (the end of 8 week of treatment)
Method of measurement
Measurement of severity of depression based on the Hamilton Rating Scale for Depression (HRSD) score

2

Description
Incidence of treatment-related complication
Timepoint
During the intervention every week until the end of 8 week of treatment
Method of measurement
Based on the evaluation of patients' symptoms at weekly visits and incidence of any side effects related to treatment such as dry mouth, sleep disorders, headaches, digestive problems, urinary problems, sexual function problems and etc.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Fluoxetine 10 mg, once a day (Abidi Pharmaceutical Company, Iran) will be prescribed for 4 weeks and then the patients will be received Deprofade saffron capsule 20 mg per day (Tolou Gostar Bokhara Company, Iran) along with fluoxetine 10 mg for 4 weeks.
Category
Treatment - Drugs

2

Description
Control group: Fluoxetine 10 mg (Abidi Pharmaceutical Company, Iran) will be prescribed for 4 weeks and then patients receive a similar capsule containing placebo (prepared in the Faculty of Pharmacy of Ahvaz Jundishapur University) along with fluoxetine for 4 weeks (The appearance of the placebo is similar to that of saffron cap).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Ahmad Fakhri
Street address
Imam Khomeini Hospital, Azadegan St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
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Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.
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6135715794
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badavim@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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

Ahvaz University of Medical Sciences
Full name of responsible person
Masumeh Ebrahimilagha
Position
Resident
Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available