Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of effect between Ziziphus jujube fruit and benzodiazepines in patients with depression and anxiety disorders treated with selective serotonin reuptake inhibitors

Protocol summary

Study aim
Determining the effects of jujube fruit compared to benzodiazepines in patients with depression and anxiety disorder treated with SSRI

Design
Randomized clinical trial with a control group with parallel groups including 25 people in each group, one blind, randomized using block method.

Settings and conduct
This study will be conducted in the specialized psychiatric clinic of Bahlul Gonabadi Hospital. 50 patients with anxiety and depression disorders who meet the conditions to enter the study will be randomly assigned to two intervention and control groups.This study will be blinded to the analyst.

Participants/Inclusion and exclusion criteria
Entry criteria: Referees to the specialized psychiatric clinic of Bohlool Hospital in Gonabad city, who have been diagnosed with anxiety and depression based on DSM-V criteria, aged 18 to 65 years, patients who are candidates for treatment with SSRIs and benzodiazepines, having written informed consent To participate in the research. Exclusion criteria: history of sensitivity to jujube fruit consumption, consumption of jujube or other herbal medicines during the last 4 weeks before starting the study, history of addiction, pregnancy or intention to become pregnant, breastfeeding, history of suffering from other psychiatric disorders.

Intervention groups
The test and control group includes patients with anxiety and depression disorders. The test group is treated for one month with standard drug (SSRI) + jujube fruit powder, one 15 gram sachet daily, and the control group is treated with SSRI + benzodiazepine

Main outcome variables
Beck's anxiety score, Beck's Depression Score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200418047116N4**
Registration date: **2023-10-09, 1402/07/17**
Registration timing: **prospective**

Last update: **2023-10-09, 1402/07/17**
Update count: **0**

Registration date
2023-10-09, 1402/07/17

Registrant information

Name
Negar Shafaei bajestani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 5723 6833

Email address
shafaei.n@gmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-22, 1402/09/01

Expected recruitment end date
2024-08-22, 1403/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of effect between Ziziphus jujube fruit and benzodiazepines in patients with depression and anxiety disorders treated with selective serotonin reuptake inhibitors

Public title
The effect of Ziziphus jujube in the treatment of anxiety and depression

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Referees to the specialized psychiatric clinic of Bohlool Hospital in Gonabad city who have been diagnosed with anxiety and depression disorders based on DSM-V criteria. Candidate patients for treatment with SSRI and benzodiazepines, Having written informed consent to participate in the study Age 18 to 65 years
Exclusion criteria:
History of sensitivity to jujube fruit consumption (based on the individual's own report) History of addiction Pregnancy or intention to become pregnant History of other psychiatric disorders Breastfeeding Taking jujube or other herbal medicines during the last 4 weeks before the start of the study Contraindications for benzodiazepine or SSRI administration Mental retardation Taking drugs that interfere with study drugs

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In the current study, patients suffering from anxiety and depression referring to the psychiatric clinic of Allameh Bahloul Gonabadi Hospital are selected using available sampling method.In order to assign the patients to two intervention and control groups, he used the method of quadruple permutation blocks in such a way that first six possible states of the blocks.Then people are assigned to the control group (A) and the intervention group (B) based on the block corresponding to the selected number. It will continue until the end of the sample volume

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, blinding is done only for the analyst in such a way that two treatment groups with two codes A and B will be determined in the software, and the analyst will not know the nature of the treatment codes.

Placebo
Not used

Assignment
Parallel

Other design features
In this study, when obtaining written consent, the possibility of complications for the patients (whether they are in the test group or the control group) is explained, and the patients are requested to report to the project manager or the doctor in case of any complications. Notify your specialist. In case of complications, the patient can be excluded from the study. Then, depending on the type of complication and with the opinion of their specialist doctor, their symptoms are treated. The patients have a close relationship with their doctor and the project manager throughout the study period.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Gonabad University of Medical Science

Street address
Gonabad - Asian Roadside - Gonabad University of Medical Sciences

City
Gonabad

Province
Razavi Khorasan

Postal code
9691793718

Approval date
2023-01-25, 1401/11/05

Ethics committee reference number
IR.GMU.REC.1401.161

Health conditions studied

1

Description of health condition studied
anxiety

ICD-10 code
F41.9

ICD-10 code description
Anxiety disorder, unspecified

2

Description of health condition studied
depression

ICD-10 code
F32.9

ICD-10 code description
Major depressive disorder, single episode, unspecified

Primary outcomes

1

Description
Anxiety scores in the Beck questionnaire
Timepoint
Before the intervention, one month and three months after the intervention
Method of measurement
Beck anxiety questionnaire

Secondary outcomes

1

Description
Severity of Illness
Timepoint
One month and three months after the intervention
Method of measurement
Global Clinical Perception Questionnaire - Severity of Illness

2

Description
Drowsiness check
Timepoint
One month and three months after the intervention
Method of measurement
Complications survey questionnaire

Intervention groups

1

Description
Intervention group: Intervention group: Jujube powder purchased from Shayna, a 15 gram sachet once a day, will be added to the main treatment (SSRI) for one month.
Category
Treatment - Drugs

2

Description
Control group: treated with a routine drug regimen including SSRI and BZD for one month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Specialized Psychiatry Clinic of Bohlool Gonabadi Hospital
Full name of responsible person
Negar Shafaei Bajestani
Street address
Nurse St., Specialized Psychiatry Clinic of Allameh Bohlool Gonabadi Hospital
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 51 5723 6833
Email
Shafaei.n@gmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Dr. Leila Sadegh Moghadam
Street address
Dr.Mehdizade Blvd.
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 51 5722 3028
Email
info@gmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gonabad 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
Gonabad University of Medical Sciences
Full name of responsible person
Negar Shafaei Bajestani

Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Allameh Bohlool Gonabadi Hospital, Vahdat Blvd.,Saadi St.
City
Gonabad
Province
Razavi Khorasan
Postal code
9691797852
Phone
+98 51 5723 6833
Email
negar.shafaei89@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Negar Shafaei Bajestani
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Allameh Bohlool Gonabadi Hospital, Vahdat Blvd.,Saadi St.
City
Gonabad
Province
Razavi Khorasan
Postal code
9691797852
Phone
+98 51 5723 6833
Email
negar.shafaei89@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Negar Shafaei Bajestani
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Allameh Bohlool Gonabadi Hospital, Vahdat Blvd.,Saadi St.
City
Gonabad
Province
Razavi Khorasan
Postal code
9691797852
Phone
+98 51 5723 6833
Email
negar.shafaei89@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data can be shared after patients are made unidentifiable.
When the data will become available and for how long
Data can be accessible 6 months after results are published.
To whom data/document is available
The researchers in university and other scientific institutes.
Under which criteria data/document could be used
Help in managing of patients.
From where data/document is obtainable
Data can be accessible through sending an email to the corresponding author. Negar Shafaei-Bajestani negar.shafaei89@gmail.com
What processes are involved for a request to access data/document
after sending a request email to the corresponding author, data will be sent in 1 month.
Comments